



Federal Register

**Thursday,
January 4, 2001**

Part II

Department of Health and Human Services

**Health Care Financing Administration
42 CFR Parts 411 and 424
Medicare and Medicaid Programs;
Physicians' Referrals to Health Care
Entities With Which They Have Financial
Relationships; Final Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 411 and 424

[HCFA-1809-FC]

RIN 0938-AG80

Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with 90-day comment period (Phase I of this rulemaking) incorporates into regulations the provisions in paragraphs (a), (b), and (h) of section 1877 of the Social Security Act (the Act). Under section 1877, if a physician or a member of a physician's immediate family has a financial relationship with a health care entity, the physician may not make referrals to that entity for the furnishing of designated health services (DHS) under the Medicare program, unless an exception applies. The following services are DHS: clinical laboratory services; physical therapy services; occupational therapy services; radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.

In addition, section 1877 of the Act provides that an entity may not present or cause to be presented a Medicare claim or bill to any individual, third party payer, or other entity for DHS furnished under a prohibited referral, nor may we make payment for a designated health service furnished under a prohibited referral.

Paragraph (a) of section 1877 of the Act includes the general prohibition. Paragraph (b) of the Act includes exceptions that pertain to both ownership and compensation relationships, including an in-office ancillary services exception. Paragraph (h) includes definitions that are used throughout section 1877 of the Act, including the group practice definition and the definitions for each of the DHS.

We intend to publish a second final rule with comment period (Phase II of

this rulemaking) shortly addressing, to the extent necessary, the remaining sections of the Act. Phase II of this rulemaking will address comments concerning the ownership and investment exceptions in paragraphs (c) and (d) and the compensation exceptions in paragraph (e) of section 1877 of the Act. Phase II of this rulemaking will also address comments concerning the reporting requirements and sanctions provided by paragraphs (f) and (g) of the Act, respectively, and include further consideration of the general exception to the referral prohibition related to both ownership/investment and compensation for services furnished in an ambulatory surgical center (ASC), end-stage renal dialysis facility, or by a hospice in § 411.355(d) of the regulations (this exception presently is in force and effect as to clinical laboratory services). In addition, Phase II of this rulemaking will address section 1903(s) of the Act, which extends aspects of the referral prohibition to the Medicaid Program. Phase II will also address comments received in response to this rulemaking, as appropriate, and certain proposals for new exceptions to section 1877 of the Act not included in the 1998 proposed rulemaking, but suggested in the public comments.

DATES: *Effective date:* The regulations delineated in Phase I of this rulemaking are effective on January 4, 2002 except for § 424.22(d), which is effective on February 5, 2001.

Comment date: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on April 4, 2001.

ADDRESSES: Mail written comments (one original and three copies) to the following address only: Health Care Financing Administration, Department of Health and Human Services, Attn: HCFA-1809-FC, P.O. Box 8013, Baltimore, MD 21244-8013.

Since comments must be *received* by the date specified above, please allow sufficient time for mailed comments to be received timely in the event of delivery delays. If you prefer, you may deliver your written comments (one original and three copies) by courier to one of the following addresses: Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or C5-15-03, Central Building, 7500 Security Boulevard, Baltimore, MD 21244-1850. Comments mailed to the two addresses provided in this paragraph may be delayed and received too late to be considered.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-1809-FC.

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC 20201, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

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FOR FURTHER INFORMATION CONTACT: Joanne Sinsheimer, (410) 786-4620.

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we provide a document on our website, the document that we publish in the **Federal Register** is the official HCFA publication.

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I. Background

A. Legislative and Regulatory History

1. Section 1877 of the Act

Section 6204 of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101-239) (OBRA 1989), enacted on December 19, 1989, added section 1877 to the Act. Section 1877 of the Act prohibited a physician from referring a patient to an entity for clinical laboratory services for which Medicare might otherwise pay, if the physician or the physician's immediate family member had a financial relationship with the entity. The statute defined "financial relationship" as an ownership or investment interest in the entity or a compensation arrangement between the physician (or the physician's immediate family member) and the entity. The statute provided for several exceptions to the prohibition. Some applied to ownership/investment interests and compensation arrangements; others applied only to ownership/investment interests or only to compensation arrangements.

The statute further prohibited an entity from presenting or causing to be presented a Medicare claim or bill to any individual, third party payer, or other entity for clinical laboratory services furnished under a prohibited referral. Additionally, the statute

mandated refunding any amount collected under a bill for an item or service furnished under a prohibited referral. Finally, the statute imposed reporting requirements and provided for sanctions, including civil monetary penalty provisions. Section 1877 of the Act became effective on January 1, 1992.

Section 4207(e) of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508) (OBRA 1990), enacted on November 5, 1990, amended certain provisions of section 1877 of the Act to clarify definitions and reporting requirements relating to physician ownership and referral and to provide an additional exception to the prohibition.

Several subsequent laws further changed section 1877 of the Act. Section 13562 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103-66) (OBRA 1993), enacted on August 10, 1993, expanded the referral prohibition to cover 10 "designated health services," in addition to clinical laboratory services, modified some of the existing statutory exceptions, and added new exceptions. Section 152 of the Social Security Act Amendments of 1994 (SSA 1994) (Pub. L. 103-432), enacted on October 31, 1994, amended the list of designated services, effective January 1, 1995, changed the reporting requirements at section 1877(f) of the Act, and modified some of the effective dates established by OBRA 1993. Some provisions relating to referrals for clinical laboratory services were effective retroactively to January 1, 1992, while other provisions became effective on January 1, 1995.

2. Section 1903(s) of the Act

Title XIX of the Act established the Medicaid program to provide medical assistance to individuals who meet certain income and resource requirements. The States operate Medicaid programs in accordance with Federal laws and regulations and with a State plan that we approve. Though States administer the Medicaid programs, the Federal and State governments jointly finance them. We call the Federal government's share of medical assistance expenditures "Federal financial participation" (FFP).

Until OBRA 1993, there were no statutory or regulatory requirements affecting a physician's referrals for services covered under the Medicaid program. Section 13624 of OBRA 1993, entitled "Application of Medicare Rules Limiting Certain Physician Referrals," added a new paragraph (s) to section 1903 of the Act, that extends aspects of the Medicare prohibition on physician referrals to Medicaid. This provision

bars FFP in State expenditures for DHS furnished to an individual based on a physician referral that would result in a denial of payment for the services under the Medicare program if Medicare covered the services to the same extent and under the same terms and conditions as under the State Medicaid plan. The statute also made certain reporting requirements in section 1877(f) of the Act and a civil monetary penalty provision in section 1877(g)(5) (related to the reporting requirements) applicable to providers of DHS for which payment may be made under Medicaid in the same manner as they apply to providers of such services for which payment may be made under Medicare. Section 1903(s) of the Act applies to a physician's referrals made on or after December 31, 1994.

B. Regulations History

1. Regulations Published by HCFA and the Office of the Inspector General (OIG) Relating to Section 1877 of the Act

The following is a summary of the series of regulations we have published in the **Federal Register** over the past several years to implement the provisions of section 1877 of the Act, as amended, and section 1903(s) of the Act:

- On December 3, 1991, we issued an interim final rule with comment period (54 FR 61374) to set forth the reporting requirements under section 1877(f) of the Act.

- On March 11, 1992, we issued a proposed rule (57 FR 8588) to implement the self-referral prohibition and exceptions related to referrals for clinical laboratory services established by section 1877 of the Act, and amended by OBRA 1990.

- On August 14, 1995, we issued a final rule with comment period (60 FR 41914) incorporating the provisions of OBRA 1993 and SSA 1994 that relate to referrals for clinical laboratory services under section 1877 of the Act, effective January 1, 1992, and revising the March 11, 1992 proposal based on the public comments we received.

- On January 9, 1998, we issued a proposed rule (63 FR 1659) to amend the provisions of the August 1995 final rule and to reflect other changes in section 1877 of the Act enacted by OBRA 1993 and SSA 1994 that were effective January 1, 1995. These include, among other changes, the expansion of the referral prohibition to the 10 additional DHS, and the Medicaid expansion.

- On January 9, 1998, we published a final rule with comment period (63 FR 1846) incorporating into our regulations

the specific procedures we will use to issue advisory opinions, as required under section 1877(g)(6) of the Act. Section 1877(g)(6) of the Act requires that we issue written advisory opinions to outside parties concerning whether the referral of a Medicare patient by a physician for DHS (other than clinical laboratory services) is prohibited under section 1877 of the Act.

We also note that on October 20, 1993, the OIG published a proposed rule (58 FR 54096) to implement the civil money penalty provisions under sections 1877(g)(3) and (g)(4) of the Act. The OIG followed with publication of a final rule with comment period (60 FR 16580) on March 31, 1995.

2. Details About Prior Related Regulations

On August 14, 1995, we published in the **Federal Register** a final rule with comment period (60 FR 41914) that incorporated into regulations the provisions of section 1877 of the Act prohibiting physician referrals for clinical laboratory services under the Medicare program. That rule incorporated certain expansions and exceptions created by OBRA 1993, and the amendments in SSA 1994. It included only the expansions and other changes that related to prohibited referrals for clinical laboratory services that were retroactively effective to January 1, 1992, and interpreted the new provisions only in a few limited instances in which it was essential to implement the law. That rule also included our responses to the public comments we received on both the December 3, 1991 interim final rule with comment period (56 FR 61374) that established the reporting requirements under section 1877(f) of the Act, and the March 11, 1992 proposed rule (57 FR 8588) that covered section 1877 of the Act, as amended by OBRA 1990, and related to referrals for clinical laboratory services.

Because the August 1995 rule addressed only those changes made by OBRA 1993 and SSA 1994 that had a retroactive effective date of January 1, 1992, we explained our intent to later publish a proposed rule to fully implement the extensive revisions to section 1877 of the Act made by OBRA 1993 and SSA 1994, and to interpret those provisions when necessary. In the later proposed rule, we intended to include the revisions that relate to referrals for the additional DHS (including clinical laboratory services) that became effective January 1, 1995, and to implement the Medicaid expansion in section 1903(s) of the Act

that became effective for referrals made on or after December 31, 1994.

As intended, on January 9, 1998, we published the proposed rule (63 FR 1659). The rule was organized as follows: In section I (63 FR 1661 through 1663), we summarized the problems associated with physician self-referrals and the relevant legislative and regulatory background. In section II (63 FR 1663 through 1673), part A, we summarized the provisions of our proposed rule and described how we proposed to alter the final regulation covering referrals for clinical laboratory services to apply it to the additional DHS and to reflect the statutory changes in section 1877 of the Act that were effective on January 1, 1995. In section II, part B, we described the changes we proposed to make to the Medicaid regulations to incorporate section 1903(s) of the Act. In section III (63 FR 1673 through 1705), we discussed in detail how we proposed to interpret any provisions in sections 1877 and 1903(s) of the Act that we believed were ambiguous, incomplete, or that provided us with discretion. We also discussed policy changes or clarifications we proposed to make to the August 1995 rule covering referrals for clinical laboratory services. Section IV (63 FR 1705 through 1715) of the proposed rule included our responses to some of the most common questions concerning physician referrals that we received from physicians, providers, and others in the health care community. We included our interpretations of how the law applies in the situations described to us. Section V (63 FR 1715 through 1719) included a Regulatory Impact Analysis, and section VI (63 FR 1719 through 1720) covered our policy on responding to comments. The proposed regulation text appeared at 63 FR 1720 through 1728.

In the January 1998 proposed rule, we proposed to incorporate the Medicaid expansion in section 1903(s) of the Act into § 435.1012(a) (Limitation to FFP related to prohibited referrals). Section 435.1012(a) stated that no FFP was available for a State's expenditures for certain DHS, as they are defined in proposed § 411.351, furnished to an individual under the State plan. No FFP is available if the services are those furnished on the basis of a physician referral that would, if Medicare provided for coverage of the services to the same extent and under the same terms and conditions as under the State plan, result in the denial of Medicare payment for the services under §§ 411.351 through 411.360. In § 435.1012(c), we included a cross reference to the procedures we

established for individuals or entities to request advisory opinions from us on whether a physician's referrals relating to DHS (other than clinical laboratory services) are prohibited under section 1877 of the Act. Although these advisory opinions were meant to reflect our interpretation of section 1877 of the Act, they can potentially affect FFP payments to States under the Medicaid program.

Section 1877(b)(3) of the Act excepts from the referral prohibition services furnished to enrollees of certain "prepaid" health plans; however, these exceptions extend only to services furnished to Medicare beneficiaries under Medicare contracts and demonstration projects. As a result, the exception for prepaid arrangements does not apply to physicians who wish to refer in the context of the Medicaid program. In order to give effect to this exception in the Medicaid context, we included, in the January 1998 proposed rule, in § 435.1012(b) an exception for DHS furnished by managed care entities analogous to the Medicare entities excepted under section 1877(b)(3) of the Act. The new exception was meant to cover entities that provide services to Medicaid-eligible enrollees under contract with State Medicaid agencies and under certain demonstration projects. (We discussed these analogous entities in detail in the proposed rule at 63 FR 1697.)

To accommodate the Congress's subsequent creation of the Medicare+Choice (M+C) Program in the Balanced Budget Act of 1997 (Pub. L. 105-33) (BBA 1997), we included an amendment to the physician referral regulations as part of the June 26, 1998 interim final rule with comment period (63 FR 35066) establishing the M+C Program. We amended the final physician self-referral regulations covering referrals for clinical laboratory services by adding an exception in § 411.355(c)(5) for services furnished to prepaid enrollees by a coordinated care plan. We defined a coordinated care plan as such a plan, within the meaning of section 1851(a)(2)(A) of the Act, offered by an organization in accordance with a contract with us under section 1857 of the Act and the M+C regulations. We are reprinting that provision in Phase I of this rulemaking.

II. Development of Phase I of This Final Rulemaking

A. Technical Explanation of Bifurcation of the Regulation

Phase I of this rulemaking implements subsections (a) and (b) of section 1877 of the Act, and related definitions, as

applied to the Medicare program. We intend to issue Phase II of this rulemaking to cover the remainder of section 1877 of the Act, including its application to the Medicaid program, shortly.

Phase I of This Rulemaking

Given the importance of subsections (a) and (b), and the substantial changes we are making to the January 1998 proposed rule, we are proceeding with the issuance of Phase I of this rulemaking at this time. Further, we are issuing Phase I for comment and delaying its effective date for 1 year to allow individuals and entities engaged in business arrangements affected by Phase I time to restructure those arrangements to comply with the provisions of Phase I, except for § 424.22(d), which is effective February 5, 2001. The statutory provisions interpreted by Phase I remain in effect, as they have been since 1989 for clinical laboratory services and 1993 for all other DHS.

Phase I of this rulemaking differs substantially from the January 1998 proposed rule in several major respects, which include the following:

- Clarification of the definitions of DHS.
- Clarification of the concept of "indirect financial relationship" and creation of a new exception for indirect compensation arrangements.
- Substantial broadening of the in-office ancillary services exception by easing the criteria for qualifying as a group practice and conforming the supervision requirements to HCFA coverage and payment policies for the specific services.
- Expansion of the in-office ancillary services exception to cover certain DME provided in physicians' offices to patients to assist them in ambulating, and blood glucose monitors.
- Allowance of shared facilities in the same building where physicians routinely provide services that are in addition to Federal and private pay DHS.
- Exclusion of services personally performed by the referring physician from the definition of "referral."
- Creation of a new exception for compensation of faculty in academic medical centers.
- Addition of a new "risk-sharing" exception for commercial and employer-sponsored managed care plans.
- Interpretation of the "volume or value" standard for purposes of section 1877 of the Act as permitting unit of service or unit of time-based payments, so long as the unit of service or unit of time-based payment is fair market value

and does not vary over time. (The details of these and other changes are explained at length in section VI of this preamble.)

- Creation of an exception where DHS are furnished by entities that did not know of or have reason to suspect the identity of the referring physician.

In developing Phase I of this rulemaking, we have carefully reconsidered the January 1998 proposed rule given both the history and structure of section 1877 of the Act and the extensive comments we received on the January 1998 proposed regulation. We believe that Phase I of this rulemaking addresses many of the industry's primary concerns, is consistent with the statute's goals and directives, and protects beneficiaries of Federal health care programs.

Our paramount concern is to implement section 1877 of the Act consistent with congressional intent. Prior to enactment of section 1877, there were a number of studies, primarily in academic literature, that consistently found that physicians who had ownership or investment interests in entities to which they referred ordered more services than physicians without those financial relationships (some of these studies involved compensation as well). Increased utilization occurred whether the physician owned shares in a separate company that provided ancillary services or owned the equipment and provided the services as part of his or her medical practice. This correlation between financial ties and increased utilization was the impetus for section 1877 of the Act.

The approach chosen by the Congress in enacting section 1877 of the Act is preventive because it essentially prohibits many financial arrangements between physicians and entities providing DHS. Specifically, section 1877 of the Act imposes a blanket prohibition on the submission of Medicare claims (and payment to the States of FFP under the Medicaid program) for certain DHS when the service provider has a financial relationship with the referring physician, unless the financial relationship fits into one of several relatively specific exceptions. Significantly, no wrongful intent or culpable conduct is required. The primary remedy is simply nonpayment by the program, without penalties. In other words, the basic remedy is recoupment of overpayments by the program. (Of course, wrongful conduct, such as knowingly submitting a claim in violation of the prohibition, can be punished through recoupment of overpayments and imposition of

penalties, the False Claims Act, and other Federal statutory and common law remedies.)

The effect of this statutory scheme is that failure to comply with section 1877 of the Act can have a substantial financial result. For example, if a hospital has a \$5,000 consulting contract with a surgeon and the contract does not fit in an exception, every claim submitted by the hospital for Medicare beneficiaries admitted or referred by that surgeon is not payable, since all inpatient and outpatient hospital services are DHS.

While the statutory scheme of the physician self-referral prohibition is, in large part, the key to its effectiveness, it obligates us to proceed carefully in determining the scope of activities that are prohibited. In Phase I of this rulemaking, we have attempted to minimize the impact of the rule on many common physician group governance and compensation arrangements.

The potential impact of the regulation was further confirmed by the voluminous comments we received from the public and health care community in response to the January 1998 proposed rule. In addition to specific complaints and objections about the January 1998 proposed rule, the commenters expressed several general concerns, which include the following:

- The rule inappropriately intruded into the organization and delivery of medical care within physicians' offices.
- The rule, in many respects, was counter to our other long-standing policies on coverage and similar issues.
- The rule was unclear in many areas and that given the potentially serious consequences (for example, payment denial), "bright line" rules were essential.
- Some aspects of the rule, such as its treatment of indirect financial relationships, were administratively impractical or would have been prohibitively costly in terms of monitoring compliance.

With these overall considerations in mind, we have developed several criteria for evaluating our regulatory options. First, we have tried in Phase I of this rulemaking to interpret the prohibitions narrowly and the exceptions broadly, to the extent consistent with the statutory language and intent. As a practical matter, we believe that, while the statute must be implemented to achieve its intent, we should be cautious in interpreting its reach so broadly as to prohibit potentially beneficial financial arrangements. Accordingly, we have

tried to focus the regulation on financial relationships that may result in overutilization, which we believe was the main abuse at which the statute was aimed. Some provisions of the January 1998 proposed rule did not appear to address overutilization so much as other potential abuses, such as unfair competition. At the same time, we do not believe the Congress intended us to review every possible designated health service to determine its potential for overutilization. The Congress has already made that determination, and we believe that compliance with the exceptions in Phase I of this rulemaking should not cause undue disruption of the health care delivery system.

Second, a corollary of the above interpretation is that the Congress only intended section 1877 of the Act to establish a minimum threshold for acceptable financial relationships, and that potentially abusive financial relationships that may be permitted under section 1877 of the Act could still be addressed through other statutes that address health care fraud and abuse, including the anti-kickback statute (section 1128B(b) of the Act). In some instances, financial relationships that are permitted by section 1877 of the Act might merit prosecution under section 1128B(b) of the Act. Conversely, conduct that may be proscribed by section 1877 of the Act may not violate the anti-kickback statute.

Third, we have attempted to ensure that Phase I of this rulemaking will not adversely impact the medical care of Federal health care beneficiaries or other patients. In those instances in which we have determined that the provisions of Phase I of this rulemaking may impact current arrangements under which patients are receiving medical care, we have attempted to verify that there are other ways available to structure the arrangement so that patients could continue to receive the care in the same location. In almost all cases, we believe the provisions of Phase I of this rulemaking should not require substantial changes in delivery arrangements, although they may affect the referring physician's or group practice's ability to bill for the care. In other words, while the provisions of Phase I of this rulemaking may affect a physician's ability to profit financially from the provision of some services, there should be alternative providers available to provide the services in the same setting or alternative business structures that would permit the services to be provided (again, possibly without physician financial interest).

Fourth, we have revised the provisions of our January 1998 proposed

rule to conform, as much as possible, to our other policies that affect the same or similar activity. For example, we are dropping the requirement that an in-office ancillary service be supervised under the strict "direct supervision" standards of the "incident to" billing rules in favor of requiring the level of supervision that is mandated under Medicare payment and coverage rules applicable to particular DHS.

Fifth, we have attempted, as much as possible, to establish "bright line" rules so that physicians and health care entities can ensure compliance and minimize administrative costs. We agree with the commenters that as a payment rule, the regulations implementing section 1877 of the Act should establish clear standards, and we have attempted to do so within the constraints of the statutory and regulatory scheme.

We believe Phase I of this rulemaking substantially addresses the concerns raised by the commenters and, yet, is consistent with the statute. Given the breadth of the statute and the myriad of financial relationships to which it applies, it is impossible to satisfy all concerns in all instances. We have attempted to read the statute narrowly to avoid adversely impacting potentially beneficial arrangements. However, we will continue to monitor financial arrangements in the health care industry and will revisit particular regulatory decisions if we determine there is abuse or overutilization.

B. General Comments Regarding the January 1998 Proposed Rule and Responses

Comment: Many commenters echoed the general views expressed by a major physician trade association. The trade association noted that section 1877 of the Act significantly impacts the manner in which physicians deliver health care services and the manner in which they relate to one another and to other health care providers. The trade association urged us to give physicians and other providers clear direction on how to structure their financial arrangements, while providing sufficient flexibility for physicians and providers practicing in numerous and varying arrangements throughout the health care industry. The trade association and other commenters expressed concern that the January 1998 proposed rule failed to reflect the fundamental changes occurring in the health care marketplace—especially the consolidation and integration of physician practices, hospitals, and other health care entities. Indeed, the commenters perceived the proposed regulations as hostile to those changes.

The trade association and others believe that section 1877 of the Act and our regulations should focus on passive ownership and referral arrangements and not on partially and fully integrated practices demanded by the current competitive marketplace.

In addition, some commenters, including the trade association, thought that the provisions of the January 1998 proposed rule exceeded our statutory authority and imposed unnecessary and costly burdens on physicians that would harm patient access to health care facilities and services, with no apparent public benefit. In their view, the provisions of the January 1998 proposed rule (1) micro-managed physician practices in situations that do not pose a real potential for abuse, (2) limited proper and reasonable management practices, and (3) inappropriately interfered with the practice of medicine. Finally, a number of commenters suggested that, instead of promulgating a set of regulations that micro-manage the business of medicine, we could better control overutilization of DHS by monitoring the medical necessity of such services and the competency of those providing them.

Response: In developing Phase I of this rulemaking, we have been mindful of the criticism that the provisions of the January 1998 proposed rule inappropriately micro-managed physician practices. Given the purpose, structure, and scope of section 1877 of the Act, some impact on physician practices is inevitable and, frankly, intended. In Phase I of this rulemaking, we have endeavored to create "bright line" rules that are easily applied, while providing the health care industry with as much flexibility as possible. Where possible, we have tried to simplify the requirements in Phase I of this rulemaking, consistent with the clear congressional mandate to prohibit certain physician referrals tainted by physician financial self-interest. We believe Phase I of this rulemaking offers adequate flexibility to physician practices as they integrate and consolidate. For example, the revised unified business test, in the group practice definition, no longer bars cost-center or location-based distribution of a group practice's revenues from services that are not DHS. Another example: the in-office ancillary services exception covers certain ancillary services provided in facilities shared by practitioners in the same building in which they practice.

The provisions of Phase I of this rulemaking do not prevent physicians from directly providing their patients with convenient, cost-effective DHS.

Consistent with the purpose of the statute, however, the provisions of Phase I of this rulemaking do restrict the circumstances under which physicians can financially benefit from DHS they order that are provided by others. This distinction is important. Section 1877 of the Act regulates the financial relationship between referring physicians and the provider of the DHS. If a physician determines not to provide access to such services in the absence of personal profit, the decision is the physician's, not the statute's. Nothing in section 1877 of the Act restricts patient access to those services.

Finally, we cannot agree with the claim that medical necessity reviews are always an effective control on overutilization. Medical necessity reviews alone cannot control unnecessary utilization and contain health care costs. These reviews are costly and only effective in controlling the most aberrant behavior. Most importantly, the statute does not permit us—nor would we choose—to override the Congress' judgement by substituting medical necessity reviews for existing statutory standards.

Comment: Other commenters expressed concern that neither the statute nor the January 1998 proposed rule goes far enough in preventing abusive referral arrangements. Several commenters complained that allowing physicians to provide ancillary services competitively disadvantages independent ancillary services providers that are not owned or controlled by physicians. These commenters believe that an obvious referral-for-profit scheme occurs when a physician employs his or her own ancillary personnel. While most commenters who expressed this view were independent ancillary services providers, one physician also complained about fellow physicians who "churn" patients through CT/MRI machines in their offices, resulting in what the commenter termed, a "cash spigot." The commenter expressed the view that such machines are not standard in a physician's office and are solely added to physicians' offices to generate profits. Commenters also expressed concern that, in some cases, physicians do not have appropriate oversight or credentialing for the ancillary services they provide. One commenter suggested that physicians should only be permitted to provide ancillary services if no other provider is available in the area.

Response: While we believe the commenters raised valid concerns about abuses in the health care system, the plain language of the statute makes clear

that the Congress did not intend section 1877 of the Act to bar all physician-owned ancillary services facilities. To the contrary, these facilities are expressly allowed under certain specific circumstances (see sections 1877(b), (c), and (d) of the Act). Simply stated, the law is meant to prevent only the most egregious financial relationships; it does not address every potential act of fraud and abuse. As we caution throughout this preamble, section 1877 of the Act provides only a threshold check against fraud and abuse; many arrangements that are lawful under section 1877 of the Act may still violate other fraud and abuse laws, including the Federal anti-kickback statute (section 1128B(b) of the Act).

Comment: Several commenters believe that section 1877 of the Act and implementing regulations would not permit patients to receive services, such as x-rays, physical therapy, or crutches, at a physician's office or in a long term care facility where the patient resides. The commenters observed that requiring patients to seek services related to their diagnoses or treatment at several different locations is an inconvenience to patients and may require them to travel long distances to obtain services, thus, discouraging elderly or disabled patients from seeking needed health care services.

Response: The commenters misunderstand section 1877 of the Act. Section 1877 of the Act regulates financial relationships; it does not regulate the delivery of services. Section 1877 of the Act does not bar the provision of ancillary services in a physician's office, in a long term care facility, or at nearby, convenient locations. The law only imposes restrictions on a physician who makes a referral for a designated health service if he or she has a financial relationship with the ancillary services provider, such as an employment contract, an office space lease, or an ownership interest. Depending on the structure of the financial relationship, the physician may be able to profit from ordering ancillary services, thereby creating a risk that his or her orders may be motivated, in part, by personal financial considerations. Statutory and regulatory exceptions are designed to enable physicians to make ancillary services available on-site to their own patients, provided they meet the conditions set forth in the applicable exception. However, nothing in the law prevents physicians from making available convenient ancillary services when the physician has no financial interest in the provision of the services. For example, a physician may arrange for a

diagnostic services provider to perform diagnostic tests in the physician's office for which the diagnostic services provider bills, provided that any rental arrangement meets the rental exception in § 411.357(b) and does not violate the anti-kickback statute. Section 1877 of the Act reflects the Congress' unmistakable intent to recognize and accommodate the traditional role played by physicians in the delivery of ancillary services to their patients, while constraining the abuse of the public fisc that results when physician referrals are driven by financial incentives. These regulations reflect that policy balance.

Comment: One commenter stated that we had not informed Medicare beneficiaries about the potential restrictions on their access to care under section 1877 of the Act and its regulations, or informed Medicare providers about the potential restrictions on their ability to provide ancillary services.

Response: Once both Phase I and Phase II of this rulemaking are published, we intend to educate providers further about the new regulations. Providers have been on notice as to section 1877 of the Act since 1989 with respect to clinical laboratory services and 1993 with respect to all other DHS. We intend to provide general information to beneficiaries as well. However, we do not believe beneficiaries will face the restrictions on access that the commenters contemplate. Indeed, these regulations do not restrict the provision of services to Medicare beneficiaries. If a physician chooses not to make services available to patients if he or she cannot personally benefit financially from services he or she orders, but which are provided by others, the physician is responsible for restricting access. Finally, Phase I of this rulemaking is being, and Phase II of this rulemaking will be, published in the **Federal Register** and noted on the Department's website, which serves as notice to the affected community. We believe most providers will also be informed through their trade press, trade associations, and other sources.

Comment: Two commenters expressed concern that section 1877 of the Act and associated regulations would criminalize common conduct in physicians' offices.

Response: Section 1877 of the Act is a civil, not a criminal, statute. A violation of section 1877 of the Act results in nonpayment of claims and monetary sanctions. Criminal penalties or deprivation of liberty are not authorized by section 1877 of the Act.

Comment: Given the alleged complexity of the physician self-referral law and regulations and their impact on physicians' traditional business practices, several commenters requested that the effective date of the regulation be delayed to allow a reasonable time for physicians to familiarize themselves with the law and that the regulations be applied prospectively only. One commenter asked that we issue compliance guidelines. Another commenter inquired about penalties if physicians ignore the physician self-referral law.

Response: We agree with the commenters that the health care providers engaged in business arrangements affected by Phase I of this rulemaking may need time to restructure those arrangements to comply with Phase I of this rulemaking where it proscribes conduct not previously prohibited. We are, therefore, delaying the effective date of Phase I of this rulemaking for 1 year, except for § 424.22(d), which is effective February 5, 2001. In the meantime, the statute, in its entirety, remains in full force and effect with respect to all DHS listed in section 1877(h)(6) of the Act. Until the effective date of these new final regulations, the August 1995 final rule covering referrals for clinical laboratory services remains in full force and effect with respect to clinical laboratory services referrals and claims for services. Any party or parties who do not comply with the provisions of the statute, the August 1995 final rule covering referrals for clinical laboratory services, or the provisions of Phase I of this rulemaking (when it becomes effective one year from the date of publication of this **Federal Register** notice) are subject to all applicable penalties and sanctions, including those that appear in section 1877(g) of the Act. (Section 1877(g)(3) and (g)(4) sanctions are covered in an OIG regulation that was published at 60 FR 16580 on March 31, 1995.)

Because of the significant changes we are making in Phase I of this rulemaking, we are publishing these regulations in final form with a 90-day comment period. We are interested in the industry's views as to the changes we have incorporated into these regulations. Any further changes we deem necessary based on comments will be addressed in Phase II of this rulemaking or shortly thereafter.

Regarding the issue of compliance guidelines, we often issue guidelines in the form of manual provisions or operational policy letters when we find that the statute and regulations do not

address particular issues in sufficient detail.

Comment: A number of commenters objected to what they perceived as disparate treatment of solo and group practitioners. One commenter, for example, complained that under the proposed rule, a solo practitioner could provide, and keep the profits from, unlimited ancillary services provided to his or her patients, regardless of how much the physician self-refers in his or her own office, whereas a group practitioner could not.

Response: Certain disparities between the treatment of group and solo practitioners are inherent in the statutory language and structure. For example, the Congress expressly limited profit shares for group practice members to methodologies that do not directly take into account the member's DHS referrals. For obvious reasons, solo practitioners cannot be similarly limited. On the other hand, the statute allows group practices greater flexibility in terms of the locations where they can provide DHS to their patients and still come within the in-office ancillary services exception. To the extent possible, and consistent with the statute, we have tried in Phase I of this rulemaking to minimize the regulatory disparities between group and solo practitioners.

Comment: In noting that the January 1998 proposed regulation interpreted the statute to minimize any risk of fraud or abuse, several commenters stated that the marginal anti-fraud benefit of this approach is low because of additional post-1993 fraud and abuse legislation, the implementation of the anti-kickback statute, computer claims payment edits instituted by our carriers, and the creation of the National Practitioners Data Bank. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) increased funding for Medicare program safeguards such as increased coordination between Federal, State, and local authorities; investigations, audits, and inspections; and guidance to the industry. HIPAA also established the Medicare Integrity Program to encourage private entities to engage in anti-fraud activities. The BBA in 1997 also created more severe criminal penalties for health care fraud. The commenters stated that the January 1998 proposed regulation prohibits many otherwise appropriate relationships in order to deter a small proportion of inappropriate practices. The commenters asked that the final rule be more flexible and not overcompensate for potential risks because the commenters believe that post-1993 legislation and enforcement

efforts can address any inappropriate practices that may or may not be deterred by the physician self-referral law.

Response: As described above, the approach taken by the Congress in enacting section 1877 of the Act results in important differences between it and other anti-fraud and abuse measures, especially the criminal anti-kickback statute (section 1128B(b) of the Act). The laws are complementary and, although overlapping in some aspects, not redundant. We believe the Congress intended to create an array of fraud and abuse authorities to enable the government to protect the public fisc, beneficiaries of Federal programs, and honest health care providers from the corruption of the health care system by unscrupulous providers. We have revisited the January 1998 proposed rule in significant respects that minimize any unnecessary impact on providers.

Comment: A number of commenters objected to the inclusion in several of the proposed regulatory exceptions, such as the exception for fair market value transactions, of a requirement that the transaction be in compliance with the anti-kickback statute. According to the commenters, the two statutes are separate and, since the anti-kickback statute is intent-based, it would be impossible to determine with certainty whether a transaction meets the exceptions.

Response: We recognize that section 1877 of the Act and the anti-kickback statute, section 1128B(b) of the Act, are different statutes and compliance with one does not depend on compliance with the other in most situations. Notwithstanding, the Secretary's authority to create additional regulatory exceptions to section 1877 of the Act is limited by the requirement in section 1877(b)(4) that she determine that the exempted financial relationship "does not pose a risk of program or patient abuse." Section 1877 of the Act sets a *minimum* standard for acceptable financial relationships; many relationships that may not merit blanket prohibition under section 1877 of the Act can, in some circumstances and given necessary intent, violate the anti-kickback statute. If the requirement that a financial relationship comply with the anti-kickback statute were dropped, unscrupulous physicians and entities could potentially protect intentional unlawful and abusive conduct by complying with the minimal requirements of a regulatory exception created under section 1877(b)(4) of the Act. (By contrast, the statutory exceptions require no finding by the Secretary and, thus, carry no

presumptive protection under the anti-kickback statute.) In addition, some arrangements may pose a risk of improper billing or claims submission.

As a practical matter, the statutory language authorizing exceptions leaves us two choices: (1) we can limit the exceptions to those situations that pose no risk of fraud or abuse—a very stringent standard that few, if any, of the proposed regulatory exceptions meet; or (2) we can protect arrangements that, in most situations, would not pose a risk, and rely on the anti-kickback statute or other fraud and abuse laws to address any residual risk. Given the commenters' expressed preference for flexibility, we have chosen the latter alternative. Moreover, since the parties should be in compliance with the anti-kickback statute, the additional regulatory burden is minimal. In the interest of simplification, we are considering an additional exception under section 1877 of the Act for any arrangement that fits squarely in an anti-kickback "safe harbor" (section 1001.952 (Exceptions)) and plan to address the matter further in Phase II of this rulemaking.

III. The General Prohibition Under Section 1877 of the Act

Section 1877(a) of the Act establishes the basic structure and elements of the statutory prohibition: A physician cannot (1) refer patients to an entity (2) for the furnishing of DHS (3) if there is a financial relationship between the referring physician (or an immediate family member of the referring physician) and the entity, (4) unless the financial relationship fits within one of the specific exceptions in the statute or regulations issued by the Secretary. (DHS are defined in § 411.351 and discussed at length in section VIII.A of this preamble.) In this section, we discuss our interpretations of what constitutes a financial relationship, especially an indirect financial relationship, and what constitutes a referral, including an indirect referral.

Existing Law: Subject to certain exceptions, section 1877(a)(1) of the Act prohibits a physician from making a referral to an entity for the furnishing of DHS for which Medicare would otherwise pay, if the physician (or an immediate family member) has a financial relationship with the DHS entity, and prohibits the DHS entity from billing Medicare or any individual (including, but not limited to, the beneficiary), third party payer, or other entity for those services. A financial relationship is (i) either an ownership or investment interest in the DHS entity (or in another entity that holds an

ownership or investment interest in the entity) or (ii) a compensation arrangement with the DHS entity, either directly or indirectly. An ownership or investment interest may exist through equity, debt, or other means.

As defined by section 1877(h)(5) of the Act, a "referral" means a request by a physician for an item or service for which payment may be made under Medicare Part B, including a request for a consultation (including any tests or procedures ordered or performed by the consulting physician or under the supervision of the consulting physician), and the request or establishment of a plan of care by a physician that includes the furnishing of DHS, with certain exceptions for consultations by pathologists, diagnostic radiologists, and radiation oncologists.

Proposed Rule: In general, we proposed interpreting the concept of "indirect financial relationship" very broadly. In the January 1998 proposed rule, we proposed including within the reach of section 1877 of the Act any ownership or investment interest, including ownership or investment interests through intermediate entities, no matter how indirect, and we proposed to include indirect compensation relationships by tracing compensation paid by an entity furnishing DHS through other entities, regardless of how the compensation might be transformed.

We similarly proposed a broad interpretation of the phrase "referral to an entity." As defined in the statute, a referral is a "request" by a physician for a DHS. We proposed defining a "request" as any step taken after a physician performs an initial examination or a physician service on a patient that indicates that the physician believes the DHS is necessary. Under this broad reading, a referral could be either written or oral, made on medical charts or records, or indicated by a prescription or written order. We also proposed that a referral could be direct or indirect, meaning that a physician would be considered to have made a referral if he or she caused the referral to have been made by someone else (for example, an employee, a hospital discharge planner, or a staff member of a company that the physician owns or controls). We interpreted "referrals" to include DHS services subsequently performed by the referring physician.

The Final Rule: Given the significance of the general prohibition, we received many comments related to various aspects of the January 1998 proposed rule. In particular, commenters sought clarification of fundamental statutory concepts, including direct and indirect

compensation and ownership or investment arrangements. In addition, many commenters took issue with our interpretation of several of the key terms, including "referral," "consultation," and "furnishing."

We are making a number of significant changes to the general prohibition sections in Phase I of this rulemaking. These revisions include the following:

- Clarification as to what constitutes a "direct" versus an "indirect" financial arrangement, including the addition of a "knowledge" element for indirect financial relationships.

- Creation of a new exception for indirect compensation arrangements.

- Clarification that payment obligations that are secured, including those secured by a revenue stream, are among the relationships considered to be ownership or investment interests.

- Revision of the definition of "referral" to exclude services personally performed by the referring physician.

- Creation of an exception under section 1877 of the Act for entities submitting claims for DHS that did not know of and did not have reason to suspect the identity of the physician who made the DHS referral to the entity.

These changes are discussed in greater detail below. First, we address the definition of a "financial relationship;" second, we address the definition of "referral." These two aspects of the general prohibition under section 1877 of the Act are analytically distinct and require separate analyses. In general, we believe a sensible approach is to ask two questions: (1) Is there a direct or indirect financial relationship between the referring physician and the entity furnishing DHS? (2) Is there a referral for DHS from the physician to the entity? If the answer to both questions is affirmative, section 1877 of the Act is violated, unless an exception applies.

A. When Is There a Financial Relationship Between the Physician and the Entity?

The existence of a financial relationship between the referring physician (or an immediate family member) and the entity furnishing DHS is the factual predicate for triggering the application of section 1877 of the Act. Section 1877(a)(2) defines a financial relationship as: (1) An ownership or investment interest of a referring physician (or immediate family member) in the entity furnishing DHS, or (2) a compensation arrangement between the referring physician (or an immediate family member) and the entity furnishing DHS. Any financial

relationship between the referring physician and the DHS entity triggers application of the statute, even if the financial relationship is wholly unrelated to a designated health service payable by Medicare. In many instances, the financial relationship will not relate to DHS. Unless the financial relationship fits into a statutory or regulatory exception, however, referrals for DHS are prohibited.

The statute expressly contemplates that "financial relationships" include both direct and indirect ownership and investment interests and direct and indirect compensation arrangements between referring physicians and DHS entities (sections 1877(a)(2) and 1877(h)(1) of the Act, respectively). We consider a "direct" financial relationship to be an arrangement between the entity furnishing DHS and a referring physician or immediate family member with no person or entity (other than agents) interposed between them. While some commenters inquired whether particular arrangements or relationships, such as stock options or vesting in retirement plans, could be characterized as ownership or compensation arrangements, there were no substantive comments as to the underlying definition of a direct financial relationship. The specific questions raised by the commenters are addressed in the comments and responses that follow.

With respect to "indirect" financial relationships, in the preamble to the January 1998 proposed rule, we proposed to include as an "indirect" financial relationship any ownership or investment interest, including ownership or investment interests through intermediate entities, no matter how indirect, and we proposed to include indirect compensation relationships by tracing compensation paid by an entity furnishing DHS through other entities, regardless of how the compensation might be transformed. In short, we proposed very broad interpretations of indirect financial relationships.

We have generally adopted the overall interpretations of "financial relationship" in the January 1998 proposed rule, with the important exception of "indirect" financial relationships. Many commenters objected to the discussions in the preamble to the January 1998 proposed regulations relating to indirect financial relationships on the grounds that the discussions were confusing, inconsistent, administratively impracticable, or unfair. We have responded to the commenters by substantially revising the regulations

pertaining to indirect financial relationships, especially indirect compensation arrangements. As described in the paragraphs that follow, we have added a knowledge element to the definitions of "indirect" financial relationships. We have also made other significant changes in the treatment of indirect compensation arrangements.

Knowledge Element for Establishing the Existence of an Indirect Financial Arrangement

We are amending the definitions of (i) "indirect ownership or investment interest" and (ii) "indirect compensation arrangement" in § 411.354 to include a knowledge element. Many commenters expressed concern that by extending liability for indirect financial relationships to relationships involving any number of intermediate persons or entities, the January 1998 proposed regulation imposed an unfair burden on entities furnishing DHS affirmatively to ferret out and discover potential indirect financial relationships or else risk submitting improper claims because of relationships they knew nothing about. While we believe that, in most circumstances, the referring physician (or his or her immediate family member) will only be one or two degrees of separation from the entity furnishing the DHS, we have nevertheless modified the January 1998 proposed regulation to add a "knowledge" element in cases of indirect financial relationships. This modification limits exposure under section 1877 of the Act to those circumstances in which the entity furnishing DHS has actual knowledge of an indirect financial relationship or acts in reckless disregard or deliberate ignorance as to the existence of an indirect financial relationship. (We sometimes refer to this "actual knowledge or reckless disregard or deliberate ignorance" standard in this preamble by the shorthand phrase "knows or has reason to suspect.") We define the "knowledge" element in a manner consistent with Federal law, as described below.

In order to satisfy this "knowledge" element in the case of an indirect ownership or investment interest, the DHS entity need only know or have reason to suspect that the referring physician (or immediate family member) has some ownership or investment interest in the entity furnishing the DHS (or in an entity that holds an ownership or investment interest in the DHS entity). Likewise, to satisfy this "knowledge" element in the case of an indirect compensation arrangement, the DHS entity need only

know or have reason to suspect that the referring physician (or immediate family member) is receiving some aggregate compensation that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS. In other words, we are not requiring that the DHS entity have knowledge of every link in the chain of entities having financial relationships that connects the DHS entity to the referring physician (or immediate family member).

Specifically, we are providing that, in the case of indirect financial relationships, referrals will only be prohibited (and claims disallowed) if the DHS entity (i) has actual knowledge that the referring physician (or immediate family member) has an indirect financial relationship (that is, that the referring physician or immediate family member (a) has some ownership or investment interest in the DHS entity or (b) receives aggregate compensation that takes into account or otherwise reflects referrals or other business generated by the referring physician for the entity furnishing DHS), or (ii) acts in reckless disregard or deliberate ignorance of whether such an indirect financial relationship exists. Essentially, we are adopting a “knowledge” element comparable to the *scienter* standard in the Civil Monetary Penalty Law, section 1128A of the Act. This “knowledge” element generally imposes a duty of reasonable inquiry on providers. In the specific context of indirect financial relationships under section 1877 of the Act, we wish to make clear that, given the impracticability of investigating every possible indirect financial relationship involving a referring physician, the knowledge element does not impose an affirmative obligation to inquire as to indirect financial relationships. A duty of reasonable inquiry does require, however, that providers in possession of facts that would lead a reasonable person to suspect the existence of an indirect financial relationship take reasonable steps to determine whether such a financial relationship exists and, if so, whether that indirect financial relationship falls within an exception to the statute (such as the new exception for certain indirect compensation arrangements in § 411.354) or whether the DHS being furnished fall within an exception (such as the in-office ancillary services exception) *before* submitting a claim for the referred item or service or making a referral. The reasonable steps to be taken will depend on the circumstances. Reasonable steps may

include the DHS entity obtaining, in good faith, a good faith, written assurance from the referring physician (or immediate family member, as applicable) or the entity from which the referring physician (or immediate family member) receives direct compensation that the physician’s or immediate family member’s aggregate compensation is fair market value for services furnished and does not take into account or otherwise reflect referrals or other business generated by the referring physician for the DHS entity, so as to qualify under the new exception for certain indirect financial relationships in § 411.354 (discussed below). A written assurance is not determinative, however, especially if the DHS entity has knowledge of, or reason to suspect, other, contradictory evidence or information.

The addition of a knowledge requirement as an element of an improper indirect financial relationship addresses the concerns expressed by many commenters that it would be impossible continuously to investigate and uncover indirect financial relationships of every referring physician and his or her immediate family members. While the “knowing” element we are adopting may allow more claims to be paid than a requirement that would interpret the statute to impose an absolute duty to investigate (and may impose a higher evidentiary burden on the government in an enforcement action), we believe that incorporating a knowledge element in the definition of indirect financial relationships more fairly balances the burden of compliance against the risk of abuse the statute was intended to prevent. We iterate that for purposes of section 1877 of the Act, the DHS entity has no affirmative duty to inquire or investigate whether an indirect financial relationship with a referring physician (or immediate family member) exists, absent some information that would put a reasonable person on alert, and that the duty that is imposed is one of reasonable inquiry in the circumstances.

Indirect Compensation Arrangements

We have substantially revised the January 1998 proposed regulations by restructuring our approach to indirect compensation arrangements. In the January 1998 proposed regulation, we had proposed to trace compensation paid by an entity furnishing DHS through any number of other persons or entities, regardless of how the compensation might be transformed. Many commenters complained that the examples provided in different parts of the preamble to the January 1988

proposed rule were inconsistent or unclear. Upon reviewing the comments and the preamble, we understand the commenters’ confusion and have revised the provisions that apply to indirect compensation arrangements by:

- Defining “indirect compensation arrangement” to establish a “bright line” test, including the “knowing” element described above; and
- Creating a new exception under section 1877(b)(4) of the Act for certain indirect compensation arrangements that is generally consistent with the new “fair market value” exception for direct compensation arrangements.

This treatment of indirect compensation arrangements more clearly parallels the analysis and regulatory treatment of direct compensation arrangements by (i) defining the universe of financial relationships that potentially triggers disallowance of claims (that is, the definition of “indirect compensation arrangement”); and (ii) creating an exception for the subset of “indirect compensation arrangements” that will not trigger disallowance. The standards in the new exception for indirect compensation arrangements are based in large part on the standards found in the various statutory and proposed regulatory exceptions for direct compensation arrangements, especially the fair market value exception proposed in the January 1998 proposed regulations, which was received favorably by the commenters and has been incorporated into the final regulations in § 411.354(d).

The definition of an “indirect compensation arrangement” and the new exception are discussed in detail below.

- *Definition of “Indirect Compensation Arrangement.”* We have developed a simple test to identify whether an indirect compensation relationship exists. We are adopting in Phase I of this rulemaking, a definition of “indirect compensation arrangement” that has three elements: (1) There must exist between the referring physician (or immediate family member) and the DHS entity an unbroken chain of persons or entities that have financial relationships between them (that is, each link in the chain has either an ownership or investment interest or compensation arrangement with the preceding link); (2) the aggregate compensation received by the referring physician (or immediate family member) from the person or entity in the chain with which the physician has a direct financial relationship varies with, or otherwise reflects, the volume or value of referrals or other business generated by the

referring physician for the entity furnishing DHS; and (3) the DHS entity must have actual knowledge that the aggregate compensation received by the referring physician (or immediate family member) from the entity with which the physician has a direct financial relationship varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS, or act in reckless disregard or deliberate ignorance of the existence of such relationship.

The first element of the indirect compensation arrangement definition is met if there is an unbroken chain of financial relationships from the DHS entity to the referring physician (or immediate family member), regardless of the form or purpose of the payments or their relationship to the DHS referrals. This element is relatively straightforward. The unbroken chain that creates an indirect compensation arrangement can consist of any combination of excepted or unexcepted financial relationships, whether ownership or investment interests or compensation arrangements.

One issue raised by several commenters was whether an ownership or investment interest could also create a compensation arrangement. An ownership or investment interest creates a direct compensation arrangement between the owner/investor and the owned/investment entity, since the ownership or investment establishes an arrangement for the distribution of any profits or other benefits (for example, tax benefits in the case of a pass-through entity) from the venture to the owners/investors. However, when the ownership or investment interest itself meets a specific statutory exception under section 1877 of the Act, any anticipated return on investment or other remuneration flowing from the ownership or investment is similarly excepted, provided the return or other remuneration is *bona fide* and not a sham (sham returns would include, for example, use of loan proceeds to make distributions in the absence of *bona fide* profits from the venture).

An excepted financial relationship may still constitute a link in a chain that establishes an indirect compensation arrangement between a referring physician and a DHS entity. For example, if a referring physician owns an interest in a hospital that meets the exception under section 1877(d)(3) of the Act (which allows a referring physician to own an interest in a hospital as a whole, but not in a subdivision of the hospital), and the hospital contracts for services with a

clinical laboratory to which the physician refers, there would exist a chain of persons or entities having financial relationships between the referring physician and the DHS entity (referring physician → whole hospital → clinical laboratory), even though the financial relationship between the referring physician and the hospital fits in an exception. We address this issue further in the responses to comments that follow.

The second element of the definition of indirect compensation arrangement is that the aggregate compensation received by the referring physician (or immediate family member) from the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS. For the purpose of the definition of indirect compensation arrangements, we are looking at whether aggregate compensation in the direct financial relationship varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS. Accordingly, for purposes of this element, any “per service” or “per use” payment arrangement between the physician and the person or entity with which the physician has the direct relationship that is based, in whole or in part, on referrals or other business generated for the DHS entity would satisfy this element. So too, any payment or other remuneration conditioned more generally on referrals or business generated for the DHS entity would satisfy this element of the definition of “indirect compensation arrangement,” except as described in § 411.354(d)(5) (describing limited circumstances when an entity may condition compensation on referrals). (For a discussion of § 411.354(d)(5), see section V of this preamble).

If the financial arrangement between the physician (or immediate family member) and the person or entity in the chain with which the physician has the direct financial relationship is an ownership or investment interest, we will look at the relationship between that person or entity (that is, the “owned entity”) and the next person or entity in the chain with which the owned entity has a direct financial relationship (if that financial relationship is also an ownership or investment interest, we will look to the next direct financial relationship in the chain, and so forth, until we reach a

compensation arrangement with an “unowned” entity with which there is a compensation arrangement—a chain consisting entirely of owned entities is an indirect ownership or investment interest, not an indirect compensation arrangement). The inquiry then becomes whether the aggregate compensation the owned entity receives varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS.

The third element in the definition of indirect compensation arrangement is that the entity furnishing DHS must know or have reason to suspect that the referring physician’s (or immediate family member’s) aggregate compensation varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the entity furnishing the DHS. As discussed above, reason to suspect a financial relationship will trigger a duty to make an inquiry into the relationship that is reasonable in the circumstances. In the context of indirect compensation arrangements, in most cases, the referring physician (or immediate family member) will have knowledge of the basis for his or her compensation and be in the best position to assure compliance with section 1877 of the Act. Thus, as noted above, reasonable inquiry by the DHS entity may include obtaining, in good faith, a good faith, written assurance from the referring physician (or immediate family member, as applicable) or the entity from which the referring physician (or immediate family member) receives direct compensation that the physician’s or immediate family member’s aggregate compensation falls within the indirect compensation arrangement exception in § 411.354 (that is, the compensation is fair market value for services furnished and does not take into account or otherwise reflect referrals or other business generated by the referring physician for the DHS entity). As discussed below, we are creating a new exception for indirect compensation arrangements, for which we believe most nonabusive indirect compensation arrangements can readily qualify.

• *Exception for Indirect Compensation Arrangements.* While the definition of an “indirect compensation arrangement” identifies the universe of potentially improper arrangements, we recognize that many of those indirect compensation arrangements may be substantially similar to direct compensation arrangements that fit in one of the existing statutory exceptions in section 1877 of the Act or one of the

regulatory exceptions we proposed in January 1998. However, many of these indirect compensation arrangements cannot fit in those direct compensation arrangement exceptions, because the arrangements are with persons or entities that are not the person or entity furnishing DHS. Accordingly, we are creating a new exception, using the Secretary's authority under section 1877(b)(4) of the Act, to provide an exception for certain indirect compensation arrangements. The new exception would protect an indirect compensation arrangement if the following conditions are satisfied:

- The compensation received by the referring physician (or immediate family member) from the person or entity in the chain with which the referring physician (or immediate family member) has the direct financial relationship is fair market value for the items or services provided under the arrangement and does not take into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS;
- The compensation arrangement between the referring physician (or immediate family member) and the person or entity in the chain with which the physician (or immediate family member) has the direct financial relationship is set out in writing, signed by the parties, and specifies the services covered by the arrangement (in the case of a bona fide employment relationship, the arrangement need not be set out in a written contract, but it must be for identifiable services and be commercially reasonable even if no referrals are made to the employer);
- The compensation arrangement does not violate the anti-kickback statute or any laws or regulations governing billing or claims submission.

Where the financial relationship between the physician and the person or entity with whom he or she has a direct financial relationship is an ownership or investment interest, we will apply the requirements of this exception to the first compensation arrangement in the chain of relationships between the physician and the entity furnishing DHS.

For purposes of the new exception, in determining whether compensation takes into account the value or volume of referrals or other business generated by the referring physician for the DHS entity, we will apply the tests for "volume or value of referrals" and "other business generated" that are discussed in section V of this preamble and set forth in § 411.354(d) of these regulations. This is consistent with our

determination to interpret those phrases uniformly in all exceptions in which they appear. Thus, "per service" or "per use" compensation arrangements can fit in the new exception for indirect compensation arrangements, provided the "per use" or "per service" payments are fair market value for the items or services provided (and do not include any additional amount that might be attributable to the volume or value of referrals or other business generated between the referring physician and the entity furnishing DHS) and the payments do not vary during the term of the compensation arrangement in any manner that takes into account referrals to the DHS entity.

Some of the statutory and regulatory exceptions operate to exclude certain categories of services from the reach of section 1877 of the Act, when certain criteria are satisfied. In effect, services described in these exceptions are not DHS for purposes of the statute. These service-based exceptions include the physicians' services exception, in-office ancillary services exception, prepaid plans exception, and academic medical center exception, in § 411.355 of these regulations. Thus, even if there is an indirect compensation arrangement between a referring physician and an entity furnishing DHS, these exceptions may apply to referrals of the particular services described in the exception. Referrals of DHS that do not fit in a services-based exception would be prohibited unless the indirect compensation arrangement fits in the new exception for indirect compensation arrangements.

Finally, we are not adopting our interpretation in the January 1998 proposed rule with regard to common ownership or investment in the same entity (which is not the entity furnishing DHS) by the referring physician (or immediate family member) and the entity furnishing DHS. In the January 1998 proposed rule, we proposed that such common ownership would not create a compensation arrangement between the referring physician and the DHS entity. However, in the light of our modified and more limited definitions of indirect financial relationships, we have revisited the issue of common ownership. We believe that such relationships should be analyzed in the same manner as any indirect financial relationship.

We are also making the following changes in the general prohibition sections of the regulations:

- Clarification that an ownership or investment interest in a subsidiary corporation will not be considered a direct ownership or investment interest

in the parent or a sibling corporation. However, an owner of a subsidiary corporation may have an indirect financial relationship with the parent or sibling company that could trigger a violation of section 1877 of the Act.

- Treatment of stock options as creating a compensation relationship and not an ownership interest until such time as the options are exercised.
- Clarification that payment obligations that are secured, including those that are secured by a revenue stream, are considered ownership or investment interests.

In the following paragraphs, we address the specific comments we received on the discussion and proposed interpretations of financial relationships set out in the January 1998 proposed rule and our responses to them.

Comment: A number of commenters objected to the concept of "tracing" compensation from, and ownership or investment interests in, an entity furnishing DHS through any number of intermediate entities to a referring physician. According to these commenters, the administrative burden of trying to comply would be costly and ultimately impossible. These commenters believe that our proposed interpretation would place the entities furnishing the services, as well as physicians making referrals, at risk for what was unknowable given potentially complex business arrangements. One commenter suggested that we keep the same definition of financial relationship as the August 1995 final rule, which the commenter stated was limited to direct ownership and compensation arrangements.

Response: The commenter who suggested that the August 1995 final rule was limited to direct financial relationships is mistaken. In the August 1995 final rule, we defined financial relationship to include indirect financial relationships. We did not, however, expand on how we would interpret and apply the term "indirect." We believe that limiting the statutory prohibition to direct ownership and compensation arrangements would seriously weaken the statute. Unscrupulous physicians and entities furnishing DHS would simply interpose entities between themselves and funnel the money through them. Furthermore, as we stated in the preamble to the January 1998 proposed rule, the statute, by its terms, applies to indirect ownership and investment interests and compensation arrangements.

As discussed above, we have revised the treatment of indirect compensation arrangements. First, we are no longer

requiring any tracing of payments. The initial screen is simply whether there is an unbroken chain of persons or entities having financial relationships between the referring physician (or an immediate family member) and the entity furnishing DHS, regardless of the nature of the payments or financial relationships. Second, we have limited liability to instances in which the DHS entity knows or has reason to suspect that aggregate compensation received by the referring physician (or immediate family member) varies with, or otherwise reflects, the volume or value of referrals or other business generated for the DHS entity. Finally, we have made clear that absent information that would put a reasonable person on alert, a DHS entity has no affirmative duty to inquire or investigate such arrangements.

Comment: A major trade association representing physicians (and other commenters) claimed that our explanations of how we would treat several types of situations involving indirect financial relationships appeared inconsistent. Specifically, the association referred to the example of a hospital contracting with a group practice to furnish physician services and to staff the hospital, and the hospital paying the group practice for these services, and with the group practice, in turn, compensating the physicians through salaries that “in some way” reflect the hospital services. According to the January 1998 proposed rule, the physicians would have an indirect compensation relationship with the hospital that would require an exception. The commenter complained that this position is inconsistent with another example in the preamble in which we stated that, when a physician who owned a physical therapy (PT) company referred patients for treatment including PT to a skilled nursing facility (SNF) that contracted with the physician’s PT company, we would equate the physician with the PT provider.

Response: We believe the new provisions for indirect compensation arrangements address the commenters’ concerns.

In the example cited by the commenter involving the payments by a hospital to a group practice that, in turn, pays its employees a salary, we would not require evidence that the salary is “in some way” related to the hospital payment. It is enough that the hospital has a financial relationship (that is, a personal services contract) with the medical group, which, in turn, has a financial relationship with its employees. Since there is an unbroken

chain of financial relationships between the referring physician and the DHS entity, the first element in the indirect compensation definition is satisfied.

The second element of the definition of an indirect compensation arrangement would be satisfied if the aggregate compensation to the referring physician from the medical group varied with, or otherwise reflected, the volume or value of referrals or other business generated by the referring physician for the DHS entity (that is, the hospital)—a fact that should be relatively easy to establish.

The final element in the definition of an indirect compensation relationship requires that the hospital (that is, the DHS entity) (i) have actual knowledge or reason to suspect that the referring physician is receiving compensation from the medical group (that is, the entity in the chain with which the referring physician has a direct financial relationship) that varies with, or otherwise reflects, the volume or value of referrals or other business generated for the hospital.

Indirect compensation arrangements that do not fit in the new exception for such arrangements can be restructured or abandoned. Arrangements under which a referring physician receives compensation tied to the volume or value of his or her referrals or other business generated for a DHS entity are the very arrangements at which section 1877 of the Act is targeted.

Commenters claimed that our discussion at 63 FR 1710 in the preamble of the January 1998 proposed rule was confusing because of the way we described a physician’s referrals to a SNF, which, in turn, referred the patients to a PT company in which the referring physician had an ownership interest and which billed Medicare directly for services to SNF patients. In that example, the referring physician had a direct financial relationship (ownership) with the PT company. There was no indirect financial relationship involving the SNF. Rather, the referring physician had a referral arrangement with the SNF, but not a financial relationship, and the SNF had a referral arrangement with the PT provider, but not a financial relationship. We think the issue in the example is whether, by sending patients to the SNF, the physician is making referrals to the PT provider, with which the physician has a direct financial relationship. We discuss that issue in the following section on referrals.

However, we think it useful to reconsider the example in light of consolidated billing for SNFs. (We note that consolidated billing should not be

confused with composite rate payments. Consolidated billing is a process for submitting claims while composite rate payment constitutes a distinct payment methodology.) Under consolidated billing, the SNF in the example will be billing the PT services directly to Medicare. In this situation, there would be an indirect compensation relationship between the SNF—which is now the DHS entity—and the referring physician. Since the SNF would be purchasing PT services from the PT company owned by the referring physician, a financial relationship would exist between the SNF and the PT company, and the physician’s ownership interest in the PT company would complete the chain (SNF→PT company→referring physician). Thus, the first element of the definition of an indirect compensation arrangement would be satisfied. With respect to the second element, the financial relationship between the referring physician and the person or entity in the chain with which the referring physician has a direct financial relationship (that is, the PT company) is an investment interest. Accordingly, we look to the compensation paid by the SNF to the owned entity (that is, the PT company) in order to see if the second element is satisfied. Since the PT company is compensated on a per service basis that reflects referrals by the referring physician to the SNF, the second element is met. Assuming knowledge on the part of the SNF, there would be an indirect compensation arrangement, and the issue becomes whether the indirect compensation arrangement satisfies the new exception for indirect compensation arrangements in § 411.354.

Comment: Several commenters stated that when there is a chain of payments that begins with a payment by a provider of DHS to another entity controlled by it, the first payment outside the entities under common control should be the arrangement that has to meet an exception. For example, in looking at payments from a hospital to a physician group practice that is wholly owned by the hospital for hospital staffing and subsequent payments from the group to its employed physicians, the payments that would need to qualify for an exception are the payments to the employed physicians. One commenter proposed that when tracing indirect financial relationships, the inquiry should end any time a payment in the chain meets an exception.

Response: The first commenters’ suggested approach is problematic because the “volume or value” standard

for the employed physician's compensation is measured based on referrals to the physician's employer, the medical group. Applying the commenters' proposed test to the example, the medical group could pay the physician employees based on the volume and value of referrals and business generated for the hospital and still comply with the employment exception. Phase I of this rulemaking would require that the compensation to the physicians *not* vary with or otherwise reflect either referrals to the group (to comply with the employee exception) or referrals to, or other business generated for, the hospital (so that it does not qualify as an indirect compensation relationship). To the extent that the compensation paid to the physicians did vary based on referrals or other business generated for the hospital, the arrangement would still be protected if it complied with the new indirect compensation arrangements exception in § 411.354.

We also considered, but ultimately rejected, the second commenter's proposal that the inquiry end any time a financial relationship fits in an exception. The fact that one financial arrangement meets an exception does not necessarily prevent the referring physician from receiving payments based on DHS referrals to a DHS entity. For example, if a person or entity owns both a group practice and a DHS entity, a compensation arrangement with a physician employee of the group practice could fit in an exception so long as it did not take into account referrals between the employee and the group practice. The exception would not, however, prevent the compensation arrangement from taking into account referrals or other business generated by the physician employee for the DHS entity.

Having considered the several views of the commenters, we believe that Phase I of this rulemaking strikes a balance that protects the Medicare program while limiting the reach of the regulation to abusive relationships. Under Phase I of this rulemaking, there would be an unbroken chain of financial relationships (the DHS entity → the owner → medical group → referring physician). However, unless the compensation received by the employed physician varies with or otherwise reflects his or her referrals to, or other business generated for, the DHS entity, and the DHS entity has the requisite knowledge, there would not be an indirect compensation arrangement. If there were, the arrangement would have to meet an applicable exception.

Comment: One commenter asked whether there would be an indirect compensation arrangement if an employed physician refers patients for DHS to an entity that has an ownership or investment interest in the physician's employer.

Response: There may be an indirect compensation arrangement if a physician refers patients for DHS to an entity that has an ownership or investment interest in the physician's employer, since the physician would be referring to a DHS entity that has a financial relationship (ownership or investment) with an entity that has a financial relationship (compensation) with the physician. If the referring physician's compensation from his or her employer reflected DHS referrals or other business generated by the referring physician for the entity providing the DHS, and the DHS entity had actual knowledge or reason to suspect that the physician's aggregate compensation reflected the volume or value of referrals or other business for the DHS entity, there would be an indirect compensation arrangement. Unless the arrangement fit in the new indirect compensation arrangements or another exception, referrals to the entity would be prohibited.

Comment: Another commenter asked whether a physician's referrals would be prohibited in a situation involving a physician practice management company (PPMC). Specifically, the commenter asked about a referring physician who has an ownership or investment interest in a PPMC, which, in turn, controls a captive professional corporation (PC) through a web of legal agreements, including a long-term management contract. The physician refers patients for DHS to the captive professional corporation.

Response: In the scenario described by the commenter, there is very likely an indirect compensation arrangement, since the captive PC has a financial relationship with the PPMC (the management contract), which has a financial relationship (ownership or investment) with the referring physician. Since the financial relationship between the physician and the entity in the chain of financial relationships with which the physician has a direct financial relationship (that is, the PPMC) is an ownership or investment interest, we look to the compensation arrangement between the owned entity (that is, the PPMC) and the next entity in the chain, in this case, the captive PC, to determine whether the second element of the test for an indirect compensation arrangement is met. Accordingly, if the entity

furnishing the DHS (the captive PC in this example) knows or has reason to suspect that the PPMC's compensation from the captive PC varies with, or otherwise reflects, the value or volume of the captive PC's business (and consequently varies, in the aggregate, based on the referring physician's DHS referrals to the captive PC), there would be an indirect financial relationship between the captive PC and the referring physician. Unless the indirect compensation arrangement fits in the new indirect compensation arrangements or another exception, the physician could not refer DHS to the captive PC, and the captive PC could not submit claims for those DHS referrals.

Comment: Several commenters objected to our proposal that a physician can receive indirect compensation through a nonprofit enterprise if the enterprise is controlled by an individual who is in a position to "influence" the physician's referrals. The example was the owner of a clinical laboratory who is also the director of research at a nonprofit research facility that could provide physician research grants in exchange for referrals to the laboratory.

Response: The issue is whether there is a prohibited indirect financial relationship between the DHS entity (the clinical laboratory) and the referring physician. Assuming there is a financial relationship between the owner of the clinical laboratory and the nonprofit research facility, there would be a chain of persons or entities with financial relationships (clinical laboratory → research director → not-for-profit → referring physician), and the issues become (i) whether the aggregate amount of the research grants to the referring physician varies with, or otherwise reflects, the value or volume of referrals or other business generated by the referring physician for the clinical laboratory, (ii) whether the clinical laboratory knows of or has reason to suspect that the referring physician's aggregate compensation under the research grants varies with, or otherwise reflects, the volume or value of referrals or other business generated for the clinical laboratory, and (iii) if there is an indirect financial relationship, whether an exception applies. Of course, even if there is no financial relationship between the clinical laboratory and the nonprofit research facility, there could be a violation of the anti-kickback statute, section 1128B(b) of the Act, in the situation described in the comment.

Comment: Several commenters stated that compensation derived from an

ownership or investment interest (for example, a return on an investment interest or a dividend) should not give rise to indirect compensation. To support this position, they referred to discussions in the preamble to the January 1998 proposed rule and in the preamble to the August 1995 final regulations, in which we stated that compensation derived from, or ancillary to, an investment interest that qualified for an investment exception under sections 1877 (b) through (d) of the Act would not also have to meet a compensation exception.

Response: We agree with the commenters that dividends or profit distributions from an ownership or investment interest that qualifies for an ownership or investment interest exception under sections 1877(b) through (d) of the Act do not also have to meet a separate compensation exception. In other words, the ownership and investment exceptions in the statute protect the ownership or investment interest and any corresponding return on the excepted investment. Our discussion in the preamble to the January 1998 proposed rule specifically referenced and clarified the August 1995 final rule preamble discussion, which was limited to the issue of whether distributions from an excepted investment interest (that is, an ownership or investment interest protected under sections 1877(b) through (d) of the Act) had to meet an additional exception for compensation arrangements. Nothing in either preamble discussion was intended to be interpreted as saying that any other ownership or investment interests (that is, ownership or investment interests that are not specifically excepted) are not compensation arrangements. We believe that an ownership or investment interest (including distributions from the interest) creates a compensation arrangement, as defined in section 1877(h)(1)(A) of the Act, between the owner/investor and the owned/investment entity and can be part of a chain of persons or entities having financial relationships that create an indirect compensation arrangement.

Without this interpretation, unscrupulous physicians could evade section 1877 of the Act by simply interposing a shell entity, which they own, between themselves and the DHS entity (which they do not own) and taking out the compensation as dividends. In short, they would simply launder the compensation through the shell investment entity.

Comment: Another commenter suggested that a loan and any interest payments should be treated as either

ownership or compensation, but not both.

Response: We agree with the commenter. If a loan qualifies as a protected ownership or investment interest, the interest payments do not create a separate compensation arrangement. Accordingly, the interest payments need not satisfy a separate compensation exception.

Comment: A number of commenters asked that we clarify that an investment in a subsidiary that does not furnish DHS is not necessarily an ownership interest in the parent or a sibling corporation.

Response: An ownership or investment interest in a subsidiary company is neither an ownership or investment interest in the parent company, nor in any other subsidiary of the parent, unless the subsidiary company itself has an ownership or investment interest in the parent or such other subsidiaries. However, an owner of a subsidiary company may have an indirect financial relationship with the parent or sibling company that could trigger a violation of section 1877 of the Act.

Comment: One commenter objected to the suggestion in the preamble to the January 1998 proposed rule that an interest in a retirement plan might be treated as an ownership or investment interest. Another commenter stated that an unsecured loan that was subordinated to an entity's credit facility should not be treated as an ownership or investment interest.

Response: We are persuaded by the logic of the commenter and, accordingly, we withdraw the statement in the preamble to the January 1998 proposed rule that an interest in a retirement plan might be treated as an ownership or investment interest for purposes of section 1877 of the Act. We will consider contributions (including employer contributions) to retirement plans to be part of an employee's overall compensation arrangement with his or her employer. We also agree that an unsecured loan that is subordinated to a credit facility is a compensation arrangement and not an ownership or investment interest for purposes of section 1877 of the Act.

Comment: Another commenter stated that secured debt given by a not-for-profit hospital, as part of its acquisition of medical practices, should not be treated as an ownership or investment interest in the hospital, but as compensation.

Response: Section 1877(a)(2) of the Act provides that "an ownership or investment interest * * * may be through equity, debt or other means."

Accordingly, we believe that loans, bonds, or other financial instruments that are secured with an entity's property or revenue, or a portion thereof, constitute investment interests within the meaning of section 1877 of the Act. In addition, a contrary reading would result in disparate treatment of entities based on their organizational status.

Comment: One commenter asserted that stock options should be treated as either ownership or investment interests or compensation arrangements, but not both. Another commenter stated that stock options should be treated as compensation and not ownership since they do not carry voting rights or the right to dividends and must be sold upon conversion.

Response: In Phase I of this rulemaking, we are revising the rule to treat stock options as compensation at the time they are awarded. At the time they are exercised or converted, they create an ownership or investment interest and must meet an appropriate exception. Any dividends or profit distributions derived from an excepted stock ownership or investment interest would not have to meet a separate compensation exception.

Comment: Another commenter stated that stock options could be structured to discourage referrals for DHS.

Response: The fact that a particular financial arrangement might be structured to discourage referrals does not provide a basis for creating an exception. The statute is intended to remove incentives to overutilize by prohibiting certain financial relationships. If application of the statute required a case-by-case examination to determine the effect of the financial relationship, the statute's efficacy would be undermined.

Comment: One commenter suggested that the determination of whether a convertible security is a compensation arrangement or an ownership or investment interest should depend on which party has the right to convert the security. According to the commenter, if the DHS entity has the right to convert the security, the interest should be treated as compensation until conversion.

Response: We are applying the same approach to convertible securities as we are applying to stock options, and we will classify them as compensation until they are converted into equity. However, many convertible securities are bonds that can be converted into stock. Since bonds are typically secured debt, bonds will be treated as an ownership or investment interest.

B. When Does a Physician Make a Referral?

As defined by section 1877(h)(5) of the Act, a "referral" means a request by a physician for an item or service for which payment may be made under Medicare Part B, including a request for a consultation (including any tests or procedures ordered or performed by the consulting physician or under the supervision of the consulting physician), and the request or establishment of a plan of care by a physician that includes the furnishing of DHS, with certain exceptions for consultations by pathologists, diagnostic radiologists, and radiation oncologists. In the January 1998 proposed rule, we interpreted "referral" to mean any request by a physician for a service, including services subsequently performed by the physician. We proposed defining a "request" as any step taken after a physician performs an initial examination or a physician service on a patient that indicates that the physician believes the service is necessary. Under this broad definition, a referral could be either written or oral, made on medical charts or records, or indicated by a prescription or written order. We also proposed that a referral could be direct or indirect, meaning that a physician would be considered to have made a referral if he or she caused the referral to have been made by someone else (for example, an employee, a hospital discharge planner, or a staff member of a company that the physician owns or controls). As a general principle, we proposed that a physician may "cause" a referral to be made if he or she has the ability to control or influence the individual who selects the entity that furnishes the DHS.

In response to the public comments, we are making several significant changes to the definition of "referral" in Phase I of this rulemaking. These changes include the following:

- Revision of the definition of "referral" to exclude services performed personally by the referring physician. Simply stated, we are persuaded that a physician cannot make a "request" of himself or herself for services he or she personally performs. However, a physician can make a "request" of others, including, without limitation, his or her employees, co-workers, or independent contractors. These requests are "referrals" under section 1877 of the Act (although many of them will fit in an exception). We continue to believe that a referral can occur in a wide variety of formats, written, oral, or

electronic, depending on the particular service.

- Adding an exception using our regulatory authority under section 1877(b)(4) of the Act for certain referrals of DHS to an entity with which the referring physician has a prohibited financial relationship that are "indirect" referrals (for example, when a physician has caused a referral to be made by someone else or has directed or routed a referral through an intermediary) or are oral referrals (that is, no written request or other documentation that would identify the referring physician is required). A claim by the entity furnishing the DHS may be paid for purposes of section 1877 of the Act if the entity did not know or have reason to suspect the identity of the referring physician. In these circumstances, there is minimal risk of patient or program abuse by the entity submitting the claim (provided that the claim is otherwise valid).

- Clarification of the definition of a "consultation." In light of the clarifications relating to indirect and oral referrals described above, the practical significance of the definition of a "consultation" is substantially reduced.

We believe that these changes address many of the concerns expressed by commenters. In particular, we have endeavored to respond to the perceived harshness of section 1877 of the Act by creating a narrow exception under our section 1877(b)(4) authority. If the entity furnishing DHS knows of or has reason to suspect the identity of the physician who prescribed or ordered the DHS or made the referral, the DHS entity may not submit a claim for the services. If the physician who prescribes or orders a DHS is someone with whom the DHS entity has a prohibited financial relationship, we think a reasonable DHS entity should suspect that the physician referred the patient to the entity, absent some credible evidence to the contrary.

In the following paragraphs, we discuss and respond to the comments we received on the proposed interpretations of "referral" and "consultation" as published in the January 1998 proposed rule.

1. "Referral"

Comment: Many commenters objected to our interpretation in the January 1998 proposed rule that a service ordered and personally performed by a physician is a referral within the meaning of section 1877 of the Act. Commenters asked us to clarify that there is no referral if the referring physician personally performs the service. Similarly, some commenters sought clarification that there is no

referral if the services are "incident to" services personally performed by the referring physician.

Response: We are persuaded by the commenters that a physician does not make a "request," in the ordinary sense of that term, if he or she personally performs a designated health service. We agree it does not make sense to consider work that a referring physician initiates and personally performs as a referral to an entity. Thus, we are amending our definition of "referral" to exclude services that are personally performed by the referring physician (that is, the referring physician physically performs the service), and we are revising our definition of "entity" to clarify that the referring physician himself or herself is not an entity for purposes of section 1877 of the Act (although the physician's practice is an entity). All other Medicare-covered DHS performed at the request of a referring physician are "referrals" for purposes of section 1877 of the Act. A service performed by a hospital for which the hospital bills the technical or facility component of the charge would be a referred service. In such circumstances, however, the physician's service performed at the hospital for which the physician would bill Part B would not be a referred service.

With respect to services performed by others, including a physician's employees, we think the issue is more complicated. Services performed by others are reasonably considered to be performed as a result of a "request." Moreover, the statutory language in section 1877(h)(4)(B)(i) of the Act indicates that the Congress considered there to be a difference between personally performed services and services performed by others. On balance, we have chosen to include services performed by others, including a physician's employees, in the definition of referral. We are concerned that a blanket rule exempting services performed by a physician's employees from the definition of "referral" could, in some circumstances, undermine the intent of section 1877 of the Act. For example, by stationing employees in off-site DHS facilities, a physician practice could circumvent the statutory "building" requirements of the in-office ancillary services exception.

Even the more limited suggestion made by some commenters that there should be no "referral" if an employee's services are properly billable as "incident to" a physician's personally performed services could result in circumvention of the "building" requirements in some cases.

However, we believe the definition of “referral” we are adopting here—in conjunction with the in-office ancillary services exception—strikes an appropriate balance. Under the final rule, services performed by anyone other than the referring physician (whether an employee, a staff member, or a member of the physician’s group practice) is a “referral” for purposes of section 1877 of the Act. Thus, services performed by a physician’s employees will be considered “referrals”. However, in most cases, such referrals will be permitted under the in-office ancillary services exception, which is substantially broader in this final rule than in the 1998 proposed rule. Services performed by employees that do not meet the “same building” or “centralized building” tests (as applicable, depending on whether the physician is a solo or group practitioner) will be prohibited unless another exception applies.

We recognize that, in many cases, services performed by a physician’s employees are, for practical purposes, tantamount to services performed by the physician (for example, a physician’s assistant applying a neck brace ordered by a physician for an individual who has been in an auto accident, when the face-to-face encounter with the patient, including the physical examination by the physician, indicates the need for a properly adjusted neck brace.) While such services are included in the definition of “referral” under this final rule, given the significance of this issue, we are soliciting comments as to whether, and under what conditions, services performed by a physician’s employees could be treated as the physician’s personally performed services under section 1877 of the Act.

Comment: A commenter asked that we clarify that a plan of care that includes the provision of DHS by the physician establishing the plan of care is not a referral. If not clarified as suggested, the commenter believes that the physician would effectively be barred from treating his or her own patients.

Response: If the DHS are personally performed by the physician who established the plan of care, there would be no referral as to those personally performed services.

Comment: Some commenters objected to our proposed presumption that a physician has referred his or her patient to an entity for the furnishing of DHS if the patient obtains the services from the entity with which the physician has a financial relationship. One commenter described the following scenario: A physician orally tells a patient or

another person that the patient needs a designated health service. The patient obtains the service from an entity with which the physician has a prohibited financial relationship. The entity does not know (and cannot know) that the physician orally told the patient (or other person) that the service was needed. The commenter sought clarification as to the application of section 1877 of the Act in these circumstances.

Response: We are establishing an exception for indirect and oral referrals. When there is no written order or other documentation of the referral, the issue is whether the DHS provider knows or has reason to suspect the identity of the physician who prescribed or ordered the DHS or made the referral.

Comment: Several commenters sought clarification that a physician’s ordering, dispensing, or prescribing of drugs does not constitute a referral to the manufacturer of the drugs. The commenters noted that the manufacturers are not entities that furnish DHS (that is, outpatient prescription drugs) to patients. Rather, furnishing of DHS is performed by physicians, pharmacies, hospitals, and clinics.

Response: We agree that, in most cases, drug manufacturers are not entities that furnish DHS to patients for purposes of section 1877 of the Act, and, therefore, the ordering, dispensing, or prescribing of drugs would not constitute a referral to the manufacturer of the drugs. However, manufacturer-owned or -affiliated retail pharmacy operations, or other health care providers may be entities for purposes of section 1877 of the Act, if they furnish DHS to patients.

Comment: A commenter recommended that activities that a solo practitioner performs as a customary and integral part of patient treatment should not be considered a “referral.”

Response: We find the commenter’s proposed language too vague to be used in creating a standard. We believe our revised definition of “referral” that excludes personally performed services and our changes to the in-office ancillary services exception (see section VII.B.1 of this preamble) adequately address the commenter’s concerns.

Comment: A commenter stated that referrals for DHS by a nonphysician professional employee of a group practice, such as a nurse practitioner or a physician assistant, should not be imputed to a physician member of the group practice, when the nonphysician is authorized and licensed to prescribe treatment on his or her own and can make independent decisions regarding

referrals. For example, if a nurse practitioner, staffing a group practice office without a physician member present, orders and performs a plain x-ray, the referral for the x-ray should not be imputed to a physician member of the group practice. If the referral is imputed, the service may not qualify under the in-office ancillary services exception, because it is not personally performed by the referring physician, another physician in the group practice, or a person who is directly supervised by the referring physician or another group practice physician. Alternatively, the commenter suggested that we modify the “direct supervision” standard to mirror our payment and coverage requirements to enable “imputed” referrals by a nurse practitioner and a physician assistant to fit in the in-office ancillary services exception.

Response: As previously stated, we are revising the “direct supervision” standard in the in-office ancillary services exception to mirror our payment and coverage requirements. (See discussion in section VI.B.2 of this preamble.) This change should address the concern identified by the commenter.

We believe that the question of whether a referral by a nurse practitioner or a physician assistant should be imputed to an employer physician will depend on the facts and circumstances of the referral. The inquiry is whether the physician controls or influences the nonphysician’s referral. The Congress and HHS have recognized that many nurse practitioners and physician assistants are independent providers authorized and licensed to prescribe treatment and make independent decisions regarding referrals. However, these practitioners do not always act independently of their employers. For example, sometimes services of a nonphysician practitioner are billed “incident to” a physician service rather than directly under the nonphysician’s independent billing number. In short, we are concerned that physicians could attempt to circumvent section 1877 of the Act by funneling referrals through nonphysician practitioners. We believe the change in the supervision requirement affords sufficient protection for legitimate arrangements.

Comment: Several commenters were confused by our discussion in the preamble to the January 1998 proposed rule at 63 FR 1710 of a situation in which a physician who owned a physical therapy (PT) company referred patients for treatment, including PT, to a skilled nursing facility (SNF) that

contracted with the physician's PT company. In the preamble, we indicated that we would analyze the arrangement as an indirect compensation arrangement and equate the physician with the PT provider.

Response: In the preamble of the January 1998 proposed rule, we suggested that the critical factor would be the degree of control the physician had over the PT provider and the extent of the PT provider's relationship with the SNF. We are abandoning that analysis. We think the proper focus is whether the physician is making a referral to the PT provider within the meaning of section 1877 of the Act. In other words, we believe that a physician can make a referral of DHS "to an entity" even though the referral is first directed or routed through another person or entity, provided the physician has reason to know the identity of the actual provider of the service. In the SNF/PT provider example, the relevant inquiry is whether the physician has made a referral, directly or indirectly, to the entity furnishing DHS, in other words, whether he or she is referring "to" that entity. Accordingly, if the physician referring the patient to the SNF knows that the PT company in which he or she has an investment interest will furnish DHS to the patient or could reasonably be expected to know that the PT company will actually furnish DHS to the patient, the referral is a referral "to the entity" and is prohibited, unless an exception applies. Similarly, where the PT company knows or has reason to suspect that the referral for DHS came from a referring physician with whom the PT company has a prohibited financial relationship, the PT company cannot submit the claim for the DHS. The PT/SNF example will be affected by the advent of full consolidated billing for SNFs, as described above in the responses to comments on indirect compensation arrangements.

To trigger section 1877 of the Act, the direction or steering of a patient "to an entity" does not need to be in writing, nor does it have to be absolute; it need only be reasonably intended to result in the patient receiving the service from the entity. Thus, for example, when a physician provides an order or prescription for a DHS to a patient that ostensibly can be filled by any of a number of entities and then suggests or informs the patient that the order can be serviced by a particular entity, there would be a referral "to" that entity. Given the administrative burden on entities presenting claims, in the context of an indirect financial relationship, we believe a claim for DHS should be

subject to nonpayment unless the entity does not know that, and does not have reason to suspect that, the referring physician had directed the patient to the entity.

2. Consultation

The Existing Law: Section 1877(h)(5)(C) of the Act excepts from the definition of a "referral" by a "referring physician" a request by a pathologist for clinical laboratory tests or pathological examination services, a request by a radiologist for diagnostic radiology services, and a request by a radiation oncologist for radiation therapy, if the services are furnished by, or under the supervision of, the specialist, pursuant to a consultation requested by another physician. Section 1877(h)(5)(C) creates a narrow exception from the definition of "referral" for a small subset of services provided or ordered by certain specialists pursuant to a consultation requested by another physician (the referring physician).

The Proposed Rule: In the preamble to the 1998 proposed rule, we referred to the interpretation of consultation that appeared in the March 1992 proposed rule for clinical laboratory services (57 FR 8595). There, we interpreted a consultation to be:

A professional service furnished to a patient by a physician (the consultant) at the request of the patient's attending physician. A consultation includes the history and examination of the patient as well as a written report that is transmitted to the attending physician for inclusion in the patient's permanent record. If, in the course of that consultation, the consulting physician deems it necessary to order clinical laboratory services, those services may not be ordered from a laboratory in which the referring [attending] physician has a financial interest. Other referrals, such as sending a patient to a specialist who assumes responsibility for furnishing the appropriate treatment, or providing a list of referrals for a second opinion, are not "consultations" or "referrals" that would trigger the [physician referral provision].

We did not add anything to this definition in the August 1995 final rule concerning referrals for clinical laboratory services.

Commenters to the 1998 proposed rule took issue with this interpretation for several reasons, including the requirement that the consulting physician examine and take a history of the patient, and the interpretation's failure to demarcate clearly when a consultant takes over treatment of the patient.

The Final Rule: The final rule adopts a very broad interpretation of a consultation. We want to make clear that this definition is only for the very

limited purpose of determining when a pathologist's, diagnostic radiologist's, or radiation oncologist's ordering of DHS from a facility with which he or she has an otherwise prohibited financial relationship will not prohibit submission of a claim to Medicare. *Most importantly, this definition is not intended to, and has no bearing on, coverage or payment rules relating to consultations.* Coverage and payment rules related to consultations raise many issues that are irrelevant for the very limited application of the term in section 1877 of the Act. Simply put, while there may be many difficult issues in determining when certain specialty services are consultations, as opposed to routine treatment, such difficulties are relatively rare in the context of the three exceptions in section 1877(h)(5)(C) of the Act (namely, a request by a pathologist for clinical laboratory services or pathological examination services, a request by a radiologist for diagnostic radiology services, or a request by a radiation oncologist for radiation therapy).

As a preliminary matter, we think it important to recognize that section 1877 of the Act defines referrals very broadly. Section 1877(h)(5) specifically includes referrals or requests for services made by the referring physician, as well as any DHS provided pursuant to a consultation with another physician, including DHS provided by the consulting physician or any DHS ordered by the consulting physician.

Section 1877(h)(5)(A) of the Act having established that a referral includes all DHS ordered by a consulting physician, section 1877(h)(5)(C) then carves out: (i) A request by a pathologist for clinical laboratory services or pathological examination services, (ii) a request by a radiologist for diagnostic radiology services, and (iii) a request by a radiation oncologist for radiation therapy, if the services are furnished by, or under the supervision of, the pathologist, radiologist, or radiation oncologist pursuant to a consultation requested by another physician.

The final rule adopts the following criteria to identify a consultation for purposes of section 1877:

(1) A consultation is provided by a physician whose opinion or advice regarding evaluation and/or management of a specific medical problem is requested by another physician.

(2) The request and need for the consultation is documented in the patient's medical record.

(3) After the consultation is provided, the consulting physician prepares a

written report of his or her findings, which is provided to the physician who requested the consultation.

(4) With respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation, provided the radiation oncologist communicates with the referring physician on a regular basis about the patient's course of treatment and progress.

Finally, we want to make clear that the exception in section 1877(h)(5)(C) of the Act only protects the referral of DHS from the pathologist, diagnostic radiologist, or radiation oncologist to the DHS provider. If the DHS provider—(1) knows or has reason to suspect that the referral originated from the referring physician, and (2) has a direct or indirect financial relationship with the referring physician, the DHS provider cannot submit a claim to Medicare for the DHS unless the financial relationship fits into an exception. Moreover, the referring physician may not make the referral to the consultant if he or she knows or has reason to suspect that the consultant will order DHS from an entity with which the referring physician has a direct or indirect financial relationship to which no exception applies.

Comment: A commenter suggested that the “diagnostic radiology” exception should be expanded to include other DHS performed or supervised by nonradiologist physicians to assure quality of care and access to a broad variety of services. The commenter asked that we broaden the consultation exception to include all DHS used to diagnose disease that are ordered pursuant to a consultation initiated by another physician.

Response: We agree that section 1877(h)(5)(C) of the Act creates an exception for the referrals of some specialists and not others. However, the Congress specifically excepted the requests of radiologists for diagnostic radiology services if the services are furnished by, or under the supervision of, the radiologist, pursuant to a consultation requested by another physician. It is our view that the Congress regarded most radiologists in this situation and the other excepted specialists as physicians who were not instigating a referral for services, but merely implementing the request of another physician who has already determined that the patient is likely to need radiology services. The Congress believes that, in general, a radiologist in this situation would not be likely to overutilize services.

We do not believe that we have the authority to extend this exception to other specialists, some of whom provide separate physician services to patients and would be in a position to instigate the referral for radiology.

Comment: One commenter was concerned about our willingness to exempt pathologists, radiologists, and radiation oncologists, yet require other arrangements and physicians to alter their referral methods. The commenter asserted that pathologists will order further stains or studies on specimens to aid in a diagnosis. Radiologists, not infrequently, recommend further studies as part of their interpretation, again to help make a diagnosis. The commenter stated that given the current medico-legal atmosphere, it is rare that he does not follow the suggestions of these consultants. In addition, the commenter stated that he has seen cancer patients with new or progressive diseases who are being treated by radiation oncologists without any direct input from attending or primary care physicians. In the commenter's view, these examples are standard medical practice and self-serving. Since radiologists often have an ownership interest in the diagnostic facility and pathologists in a laboratory facility, they are doubly benefitted by the referral.

Response: The statute clearly establishes special rules for diagnostic radiologists, pathologists, and radiation oncologists.

Comment: A number of commenters explained their problems with distinguishing a consultation from a referral based on their particular speciality area. For example, one commenter stated that during an active phase of an oncologic, hematologic, or pneumatologic illness, the care of the patient specific to that illness may be managed by the subspecialist and the overall care of the patient may be managed by the referring physician using the information obtained from the consultation. This commenter believes that a referral would occur only if the total care of the patient were transferred.

Another commenter asserted that rarely does a treating physician completely give up the care of a patient to another physician, and rarely does the treating physician completely retain responsibility for the care of the patient. Rather, a physician will send a patient to a specialist for testing, diagnosis, and initial treatment, and then the originating physician will take over the care of the patient.

Representing specialists who frequently perform consultations and assume the neurological care of patients at the request of referring physicians,

one commenter asserted that it is appropriate to bill for a consultation when care is transferred, rather than a lower-paying evaluation and management visit, because of the extra work for the consulting physician involved in preparing a report for the attending physician.

Response: We agree with the commenters that it can be difficult to determine whether a first physician initiating a visit to a second physician should constitute a referral to another physician or the request for a consultation with that physician. However, as discussed above, in the three specific instances identified in the statute, we think there will be little disagreement in determining when there is a consultation. In any event, for purposes of section 1877(h)(5)(C) of the Act, we are adopting a broader interpretation of a consultation than is in the coverage rules. Finally, payment and coverage for consultations are not addressed or affected by this rule.

Comment: One commenter, representing an association of radiologists, discussed the case of what happens when a patient is sent to a radiation oncologist for treatment of a tumor. The commenter stated that radiation oncology treatment occurs over a period of weeks or months, and is provided within a continuum of care involving the radiation oncologist, the referring physician, and even other physicians.

Response: We agree with the commenter and have clarified the definition to recognize that radiation therapy may extend over a prolonged period of time and still be considered to be pursuant to a consultation, provided the radiation oncologist regularly communicates with the referring physician as to the patient's care.

Comment: Commenters stated that when a referring physician sends a patient to a radiation oncologist for radiation therapy, the referring physician may not see the patient for some time. The radiation oncologist may decide during this time that the patient needs services other than radiation therapy services. The commenter asked whether the radiation oncologist's referrals for nonradiation therapy services falls within the scope of the consultation exception.

Response: Under section 1877(h)(5)(C) of the Act, for radiation oncology, only a request for radiation therapy by a radiation oncologist is not considered to be a referral. We understand that in some situations when a patient is undergoing radiation therapy, the patient's care is not supervised by a physician other than the radiation

oncologist. However, the radiation oncologist cannot send the patient for DHS other than radiation therapy services to an entity with which the radiation oncologist has a financial relationship without meeting an appropriate exception.

Comment: Section 1877(h)(5)(C) of the Act excepts DHS provided by consulting pathologists, diagnostic radiologists, and radiation oncologists if the services are furnished by, or under the supervision of, the consulting physician. A commenter inquired whether the required supervision could be delegated to a member of the consulting physician's group practice.

Response: The plain language of section 1877(h)(5)(C) of the Act does not allow for supervision by anyone other than the consulting physician. However, we are broadly interpreting the supervision requirement in this section to be consistent with the supervision requirements elsewhere in these regulations. Thus, the level of supervision required is whatever level is required under the applicable Medicare payment and coverage requirements. Furthermore, the in-office ancillary services exception may be available for services supervised by a physician in the consulting physician's group practice.

Comment: A commenter stated that neither diagnostic radiologists nor pathologists perform physical examinations on patients. An association representing certain specialists stated that the definition of a consultation should be modified so as *not to require* a patient history and physical examination except when appropriate; for example, diagnostic radiologists and nuclear medicine physicians generally do not take a patient's history or perform a medical examination. However, a nuclear medicine physician would perform a history and physical examination when a patient is referred for therapy. In addition, an association representing clinical laboratories declared that it is unlikely that a pathologist would ever see a patient or take a history from a patient. An association representing radiologists asserted that diagnostic radiologists generally do not take a patient's history or conduct a medical examination; therefore, we should clarify that a history and examination of the patient is not required as part of a radiologic consultation.

Response: For purposes of section 1877 of the Act, we agree that a consultation does not necessarily include either taking the history of a patient or performing a physical examination. Certainly, pathologists

would rarely see a patient. We do expect that, on occasion, a consulting physician, such as a radiologist, might interview a patient to gain additional information about the patient's condition, but this might not amount to a full scale history. Similarly, the radiologist might examine a patient, but focus only on a particular area of concern. We are amending our description of a "consultation" to clarify that there is no requirement that these steps be performed.

Comment: A commenter asked whether the prohibition under section 1877 of the Act is triggered when a physician, who has no financial relationship with a diagnostic imaging center, initiates a referral to the imaging center rather than to a particular radiologist.

Response: We understand the commenter to be asking whether the consultation exception set forth in section 1877(h)(5)(C) of the Act applies if the request for the consultation is made to the entity that employs or contracts with a consulting radiologist rather than to the consulting radiologist. The commenter's main concern seemed to be whether a subsequent request by the employed or contractor radiologist for diagnostic radiology services furnished by the imaging center would be protected under section 1877(h)(5)(C) of the Act. We believe that under section 1877(h)(5)(C) of the Act, the request for a consultation can be made to either a particular radiologist or an entity. Also, if the referring physician does not have a financial relationship with the diagnostic imaging center, the referral to the center is not prohibited under the general prohibition in section 1877(a) of the Act.

IV. Physician Compensation Under Section 1877 of the Act: An Overview

Many public comments addressed physician compensation issues. The statute touches on physician compensation in several places: the definition of group practice, the employee exception, and the personal services exception. The interplay of section 1877 of the Act and physician compensation is one of the most significant aspects of the self-referral law.

Obviously, the issue of physician compensation is of critical importance to the physician community. As a starting point, we do not believe that the Congress intended section 1877 of the Act to regulate physician compensation practices, except as necessary to minimize financial incentives to refer DHS to entities with which the physicians have financial relationships.

Having carefully studied the public comments and having reconsidered the statutory provisions, the legislative history, and our January 1998 regulatory proposals, we believe the following general principles govern the application of the statute to the manner in which physicians are paid:

- First, as explained in section III.B of this preamble, for purposes of section 1877 of the Act, the term "referral" does not include DHS that are personally performed by the physician. As a practical matter, the statutory language and structure indicate Congressional recognition that physicians are commonly compensated based on productivity with respect to services they personally perform.

- Second, with respect to group practices, the Congress intended to confer group practice status on *bona fide* group practices and not on loose confederations of physicians who come together as a "group" substantially in order to capture the profits of DHS under the in-office ancillary services exception to section 1877 of the Act. To that end, we proposed adding a "unified business" standard to the group practice definition, using the statutory authority the Congress conferred on the Secretary to impose additional standards on group practices. However, in response to comments, we have reconsidered the test for a "unified business"; the final regulations under Phase I of this rulemaking adopt a considerably more flexible approach to the same end. Under Phase I of this rulemaking, one of several characteristics of a "unified business" is that the group's physician compensation methodologies are established by the centralized management of the group practice. For the limited purposes of establishing that a group practice is a unified business, we think it is appropriate to look at physician compensation derived from all sources, not just from DHS. However, location- and specialty-based compensation practices are expressly permitted with respect to the distribution of revenues derived from services that are not DHS. Such practices may also be allowed for DHS, depending on the circumstances. (See the discussion of the group practice definition in section VI.C of this preamble.)

- Third, except for the limited purpose of determining whether a group practice is a unified business, the physician compensation provisions for group practices under section 1877 of the Act only affect the distribution of revenues derived from DHS. In general, these revenues are likely to comprise a relatively small portion of the total

revenues of most group practices. As we indicated in 1998, section 1877 of the Act does not affect the distribution of monies earned from other services. From a practical business standpoint, however, some group practices may find it impractical to segregate DHS revenues. These parties may find it more expedient to allocate compensation in accordance with the methods permitted for DHS revenues under section 1877 of the Act.

- Fourth, the statute implicitly recognizes that solo practitioners will keep all the profits from DHS that fit in the in-office ancillary services exception, whether performed personally or by others.

- Fifth, section 1877 of the Act contemplates that physicians—whether group practice members, independent contractors, or employees—can be paid in a manner that directly correlates to their own personal labor, including labor in the provision of DHS. In other words, “productivity,” as used in the statute, refers to the quantity and intensity of a physician’s own work, but does not include the physician’s fruitfulness in generating DHS performed by others (that is, the fruits of passive activity). “Incident to” services are not included in productivity bonuses under the statute unless the services are incident to services personally performed by a referring physician who is in a *bona fide* group practice. (“Incident to” services must meet the requirements of section 1861(s)(2)(A) of the Act and section 2050, “Services and Supplies,” of the Medicare Carriers Manual (HCFA Pub. 14–3), Part 3—Claims Process.) In the case of independent contractors under the personal service arrangements exception and employees under the *bona fide* employment exception, the amount of compensation for personal productivity is limited to fair market value for the services they personally perform. The fair market value standard in these exceptions acts as an additional check against inappropriate financial incentives. (The personal service arrangements exception, as well as several other exceptions, contains additional restrictions on compensation that varies based on the volume or value of referrals. The volume or value standard is discussed in section V of this preamble.)

- Sixth, the Congress recognized that in the case of group practices, revenues derived from DHS must be distributed to the group practice members in some fashion, even though the members generate the DHS revenue. However, the Congress wished to minimize the economic incentives to generate

unnecessary referrals of DHS.

Accordingly, the Congress permitted group practice members (and independent contractors who qualify as “physicians in the group practice”) to receive shares of the overall profits of the group, so long as those shares do not directly correlate to the volume or value of referrals generated by the member or “physician in the group practice” for DHS performed by someone else. In addition, the Congress permitted groups to pay their physicians productivity bonuses based directly on personal productivity (including services incident to personally performed services), but precluded groups from paying group practice physicians any productivity bonus based *directly* on referrals of DHS performed by someone else. As detailed below, we are establishing under Phase I of this rulemaking certain methodologies that describe compensation practices that will be deemed to be *indirectly* related to the volume or value of DHS referrals for purposes of section 1877(h)(4)(B)(i) of the Act and therefore allowable under section 1877 of the Act. Groups are free to develop their own indirect methodologies, but such methodologies are subject to case-by-case review.

V. “Volume or Value” of Referrals and “Other Business Generated” Standards: An Overview

Many of the exceptions in section 1877 of the Act covering specific kinds of compensation arrangements include as one element of the exception a requirement that the compensation not take into account the volume or value of any referrals and, in some of the exceptions, the further requirement that the compensation not take into account other business generated between the parties.

In the preamble to the January 1998 proposed regulation, we had interpreted this volume or value standard as follows:

- Compensation could be based on units of service (for example, “per use” equipment rentals) so long as the units of service did not include services provided to patients who were referred by the physician receiving the payment. For example, a physician who owned a lithotripter could rent it to a hospital on a per procedure basis, except for lithotripsies for patients referred by the physician-owner; payments for the use of the lithotripter for those patients would have to use a methodology that did not vary with referrals.

- The language “or other business generated between the parties” meant that the payment in an arrangement had to be fair market value for the services

expressly covered by the arrangement and could not include any payment for services not covered by the arrangement.

- Physician compensation arrangements that were fixed in amount but conditioned either expressly or implicitly on the physicians referring patients to a particular provider or supplier took into account the value or volume of referrals within the meaning of the statute.

After reviewing the comments received, we are substantially revising the regulation with respect to the scope of the volume or value standard. Most importantly, we are permitting time-based or unit-of-service-based payments, even when the physician receiving the payment has generated the payment through a DHS referral. We have reviewed the legislative history with respect to the exception for space and equipment leases and concluded that the Congress intended that time-based or unit-of-service-based payments be protected, so long as the payment per unit is at fair market value at inception and does not subsequently change during the lease term in any manner that takes into account DHS referrals. In the case of those exceptions that include the additional restriction that the payment not take into account “other business generated between the parties,” the per unit payment also may not take into account any other business, including non-Federal health care business, generated by the referring physician. We are interpreting the phrase “generated between the parties” to mean business generated by the referring physician for purposes of section 1877 of the Act.

Applying Phase I of this rulemaking to the lithotripter example noted above, the “per use” rental payments would be protected, even for lithotripsies performed on patients referred by the physician-owner, provided that the “per use” rental payment was at fair market value, did not vary over the lease term, and met the other requirements of the rental exception. In other words, if the “per use” payment is fair market value, we will not require a separate payment arrangement for use of the equipment on patients referred by the physician-owner. In determining whether the initial “per use” payment is at “fair market value,” we will generally look to the price a hospital would pay to rent the equipment from a company that did not have any physician ownership or investment (and thus was not in a position to generate referrals or other business—*DHS or otherwise*—for the hospital) in an arm’s-length transaction. In some cases, all the available

comparables or market values may involve transactions between entities that are in a position to refer or generate other business. In such situations, we would look to alternative valuation methodologies, including, but not limited to, cost plus reasonable rate of return on investment on leases of comparable medical equipment from disinterested lessors. (The definition of fair market value is discussed in more detail in section VII.B of this preamble.)

In the light of our interpretation of the volume or value standard as permitting unit of service or unit of time-based payments, we have determined that the additional limiting phrase "not taking into account * * * other business generated between the parties" means simply that the fixed, fair market value payment cannot take into account, or vary with, referrals of Medicare or Medicaid DHS or any other business generated by the referring physician, including other Federal and private pay business. Simply stated, section 1877 of the Act establishes a straightforward test that compensation arrangements should be at fair market value for the work or service performed or the equipment or space leased—not inflated to compensate for the physician's ability to generate other revenues.

In order to establish a "bright line" rule, we are applying this interpretation of the volume or value standard uniformly to all provisions under section 1877 of the Act and part 411 where the language appears (for example, the employee, personal service arrangements, rental of office space/equipment, fair market value, non-monetary compensation under \$300, hospital medical staff benefits, academic medical center exceptions, indirect compensation arrangements, and the group practice definition). The "other business generated" restriction applies only to those exceptions in which it expressly appears.

Consistent with this interpretation, we have determined that we will not consider the volume or value standard implicated by otherwise acceptable compensation arrangements for physician services solely because the arrangement requires the physician to refer to a particular provider as a condition of payment. So long as the payment is fixed in advance for the term of the agreement, is consistent with fair market value for the services performed (that is, the payment does not take into account the volume or value of the anticipated or required referrals), and otherwise complies with the requirements of the applicable exception, the fact that an employer or a managed care contract requires

referrals to certain providers will not vitiate the exception. Any such contract, however, must expressly provide exceptions (1) when the patient expresses a different choice, (2) when the patient's insurer determines the provider, or (3) when the referral is not in the best medical interest of the patient in the physician's judgment. We caution that these mandatory arrangements could still implicate the anti-kickback statute, depending on the facts and circumstances.

Finally, we want to clarify that ownership or investment interests that are not protected under sections 1877(b) through (d) of the Act (and are therefore compensation arrangements under section 1877(h)(1)(A) of the Act) are deemed to take into account the value or volume of referrals. We believe this view is consistent with the general prohibition on investment and ownership interests in the statute.

Our responses to comments follow below:

Comment: One commenter asked us to clarify the statement in the preamble of the January 1998 proposed rule at 63 FR 1780 that the volume or value standard that is in the compensation and other exceptions is uniformly meant to cover (and thus exclude from an exception) other business generated between the parties. Another commenter asked us to clarify that the requirement that the compensation not take into account the volume or value of referrals or other business generated between the parties refers only to referrals of DHS.

Response: The discussion of the phrase "other business generated between the parties" in the preamble to the January 1998 proposed rule caused confusion. Based on our review of the legislative history, we believe that the Congress intended the language to be a limitation on the compensation or payment formula parallel to the statutory and regulatory prohibition on taking into account referrals of DHS business. Simply stated, in the provisions in which the phrase appears, affected payments cannot be based or adjusted in any way on referrals of DHS or on any other business referred by the physician, including other Federal and private pay business.

Comment: One commenter urged us to amend the language of the regulation to correspond to the extensive discussion of the volume or value standard in the preamble.

Response: We are modifying the regulation to clarify the meaning of the volume or value standard.

Comment: One commenter asked us to clarify that a valuation of a

physician's practice could include the value of self-generated DHS in the purchase price as long as the purchase agreement was not contingent on future referrals.

Response: For purposes of section 1877 of the Act, the valuation of a physician practice could include the value of DHS in the purchase price if the DHS provided by the selling physician fit into an exception, such as the in-office ancillary services exception, and the purchase agreement (and purchase price) is not contingent on future referrals. Depending on the identity of the purchaser, however, the inclusion of the value of ancillary revenues could implicate the anti-kickback statute.

Comment: Several commenters asked us to clarify that the language requiring that the payment be fixed in advance and not be determined in a manner that takes into account the value or volume of referrals or other business generated between the parties does not require that the aggregate compensation be established in advance, but only that the methodology (for example, a rental per use, or payment per service) be fixed in advance.

Response: We are modifying the regulation to make it clear that the aggregate payment need not be specified in advance. However, if the aggregate amount is not specified, the amount of the payment on a "per use," "per service," or "per time period" basis must be fixed in advance. For example, a contract could include a fee schedule for services, provided the fee schedule is uniformly applied to all services provided to the contracting party. In addition, the payment must be fair market value compensation not taking into account the volume or value of referrals or other business generated by the referring physician either at inception or during the term of the agreement.

Comment: Commenters also wished us to clarify whether the following arrangements take into account the volume or value of referrals or other business generated between the parties: (1) Payments based on a percentage of gross revenues; (2) payments based on a percentage of collections; (3) payments based on a percentage of expenses; and (4) payments based on a percentage of a fee schedule.

Response: A compensation arrangement does not take into account the volume or value of referrals or other business generated between the parties if the compensation is fixed in advance and will result in fair market value compensation, and the compensation does not vary over the term of the

arrangement in any manner that takes into account referrals or other business generated. The first three arrangements described by the commenters are neither aggregate fixed compensation amounts, nor fixed "per service," "per use," or "per time period" payment amounts. Percentage compensation that is determined by calculating a percentage of a fluctuating or indeterminate amount, such as revenues, collections, or expenses, is not fixed in advance. Accordingly, the first three arrangements do not meet the requirement that compensation be fixed in advance. Whether the fourth arrangement mentioned by the commenters—a percentage of a fee schedule—is fixed in advance compensation depends on the circumstances. If the percentage payments are based on a single fee schedule, such that there is, in effect, a single fixed fee for each service, the arrangement meets the requirement that the compensation be fixed in advance. However, a percentage of fee schedule arrangement that bases payments on multiple fee schedules, such that there may be different fees for a particular service depending on the ultimate payer, is not fixed in advance. Thus, for example, if a physician has a contract for services with a hospital that has a chargemaster for all services, the physician can be paid a fixed percentage of that chargemaster fee schedule for each service. However, when the hospital accepts different payment amounts from different payers for a service, the physician cannot be paid a percentage of those varying amounts.

Comment: Several commenters requested that the final rule make clear that payments based on "per use" or "per service" meet the volume or value standard in the exceptions so long as the payments are at fair market value and the "per use" or "per service" amount does not change over the term of the contract based on the value or volume of referrals of DHS. The commenters stated that their position was consistent with the intent of the Congress and supported their position with language from the Conference Committee report.

Response: As described above, we are modifying the regulation to reflect the Conference Committee report, H. Rep. No. 213, 103rd Cong., 1st Sess. 814 (1993). The "per use," "per service," or "per time period" amount must reflect fair market value at inception not taking into account the volume or value of referrals and must not change over the term of the contract based on the volume or value of DHS referrals, or, when applicable, other business (that is,

other Federal or private pay business) generated by the referring physician.

Comment: One commenter specifically objected to our proposed interpretation that a "per use" payment was acceptable except when the payment was for a referral from a physician with an ownership or investment interest in the equipment. According to the commenter, the physician's ownership or investment interest should not matter so long as the physician does not have a controlling interest.

Response: We believe equipment rental arrangements are subject to abuse whether the payment received is only a small portion of the rental or the entire amount. Control is irrelevant; it is the financial incentive that has been shown repeatedly to result in overutilization. Despite the obvious potential for abuse, given the clearly expressed congressional intent in the legislative history, we are permitting "per use" payments even when the physician is generating the referrals. We wish to make clear that these arrangements may violate the anti-kickback statute.

Comment: A commenter asked that we clarify that a hospital can lease equipment on a "per use" basis to a physician for use in the physician's practice.

Response: A hospital can lease equipment to a physician for use in the physician's practice on a "per use" basis, provided the lease arrangement otherwise fits in the rental exception. As noted above, these arrangements may violate the anti-kickback statute.

Comment: Many commenters objected to our proposed interpretation in the preamble that fixed payments to a physician could be determined to take into account the volume or value of referrals if a condition or requirement for receiving the payment was that the physician refer DHS to a given entity, such as an employer or an affiliated entity. A number of commenters stated that we did not have statutory authority for our proposed interpretation. Some commenters said these arrangements were necessary to develop integrated networks and ensure quality control. Another commenter stated that the proposal would interfere with exclusive hospital-based physician relationships. One commenter argued that the proposed interpretation was inconsistent with the employee exception, while yet another stated the position was inconsistent with the common law duty of loyalty owed by an employee to his or her employer and the employer's right to set the terms and conditions of employment. Another commenter stated that the proposed

interpretation would adversely impact managed care arrangements by, in effect, requiring all managed care arrangements to meet the physician incentive plan regulations. Finally, a commenter proposed that we allow entities to require physicians to refer to a particular provider as part of a contract, except (1) when the patient expresses a different choice, (2) when the patient's insurer determines the provider, or (3) when the referral is against the physician's judgment.

Response: While we believe that payments tied to referral requirements can be abused, we agree that the proposed interpretation potentially would have had far-reaching effects, especially for managed care arrangements and group practices. We are adopting in modified form the one commenter's suggestion for appropriate conditions listed in the last sentence of the comment. We believe the suggested conditions will not impose a significant burden, since they are likely to be required anyway under existing laws, professional codes, and most contracts. Thus, so long as the referral requirement does not apply if a patient expresses a different choice, the patient's insurer determines the provider, or the referral is not in the best medical interest of the patient in the physician's judgment and the payment to the physician is fixed in advance at fair market value for the services actually rendered and does not vary based on referrals or, when applicable, other business generated by the physician, the fact that referrals may be required to be made to specific providers will not nullify an exception.

Comment: One commenter stated that the final rule should not prohibit primary care case management arrangements.

Response: As discussed in the preceding comment, we are no longer viewing these arrangements as violating the volume or value standard simply because referrals may be required to be made to certain providers. The arrangement would have to meet the other provisions of an exception.

Comment: According to two commenters, many covenants not to compete could be called into question by the proposed interpretation that fixed payments tied to referral requirements can violate the volume or value standard, a component of many of the exceptions. The commenters argued that these covenants are necessary adjuncts to many business acquisitions and personal services or management arrangements and urged us to affirm their legitimacy.

Response: The commenters were unclear as to how the proposed

interpretation would have adversely impacted covenants not to compete. A requirement to refer to a specific provider is different from an agreement not to establish a competing business. In other words, a covenant not to compete might prevent a physician from setting up a private practice or offering services that compete with the entity that purchased his or her practice. If an agreement also included the requirement that the physician refer business to the purchaser, the agreement would be suspect under the anti-kickback statute.

Comment: One commenter asked us to clarify that the discussion in the preamble about the volume or value standard applies not only to its interpretation in the context of the compensation exceptions, but also to its interpretation in the other exceptions in which the same language appears.

Response: The meaning of the volume or value standard as set forth in the preamble and regulations text under Phase I of this rulemaking applies to the standard wherever it appears in the statute and regulations.

Comment: One commenter stated that the interpretation of the volume or value standard in the January 1998 proposed rule at 63 FR 1701 would permit hospitals to pressure physicians to refer to network and other providers that the hospitals own or control.

Response: It is not clear from the comment what aspect of the proposed rule would lead the commenter to believe that this kind of coercion would occur. Nonetheless, section 1877 of the Act is limited in its application and does not address every abuse in the health care industry. The fact that a particular arrangement is not prohibited by section 1877 of the Act does not mean that the arrangement is not abusive; it simply means that a referral and submission of a claim for DHS is not prohibited under section 1877 of the Act.

VI. Exceptions Applicable to Ownership and Compensation Arrangements (Section 1877(b) of the Act)

A. Physician Services (Section 1877(b)(1) of the Act)

The Existing Law: Section 1877(b)(1) of the Act specifies that the general prohibition under section 1877 of the Act does not apply to services furnished on a referral basis, if the services are physician services, as defined in section 1861(q) of the Act, and are furnished (1) personally by another physician in the same group practice as the referring physician or (2) under the personal

supervision of another physician in the same group practice as the referring physician. Section 1861(q) defines “physicians’ services” as “professional services performed by physicians, including surgery, consultation, and home, office, and institutional calls (but not including services described in subsection (b)(6) [certain intern and resident services]).” A physician is defined in the Act as a duly licensed and authorized doctor of medicine or osteopathy, doctor of dental surgery or dental medicine, doctor of podiatric medicine, doctor of optometry, or chiropractor who meets certain qualifications specified in the Act. (See section 1861(r) of the Act.)

The August 1995 final rule incorporated this provision in § 411.355 (General exceptions to the referral prohibition related to both ownership/investment and compensation), paragraph (a) (Physician services), covering physician services as defined in § 410.20 (Physicians’ services), paragraph (a) (Included services). The definition of a physician service in § 410.20(a) generally parallels the definition in section 1861(r) of the Act, with the addition of diagnosis and therapy services. Under the August 1995 final rule, physician services need not be performed in any specific location.

The Proposed Rule: The January 1998 proposed rule retained § 411.355(a) as set forth in the August 1995 final rule. In the preamble to the January 1998 proposed rule, we noted that the exception would apply to physician services that constitute DHS under section 1877 of the Act and regulations and that the exception in the Medicare context would not apply to services performed by nonphysicians, even though furnished under a physician’s supervision, such as ancillary or “incident to” services. We interpreted “personal supervision” to mean that the group practice physician must be legally responsible for monitoring the results of any test or other designated health service and must be available to assist the individual who is furnishing the service, even though the group practice physician need not be present while the service is being furnished.

The Final Rule: In general, we believe that the physician services exception is of limited application. However, the physician services exception does afford protection for referrals of the narrow class of physician services that are included in the definitions of DHS, especially in the area of radiology. (See discussion in section VIII.A of this preamble.) The physician services exception enables physicians in group practices to make referrals for physician

services that are DHS within their group practices. In addition, the in-office ancillary services exception may also apply, depending on the circumstances. We are interpreting the physician services exception to apply to referrals to (or referral services supervised by) a member of the group practice or an independent contractor who qualifies as a “physician in the group” as defined in § 411.351 (Definitions).

In particular, we are incorporating the physician services exception in § 411.355(a) as proposed in our January 1998 proposed rule, with the following modifications:

First, we are interpreting “personal supervision” to correspond with our revised interpretation of “direct supervision” in the context of the in-office ancillary services exception. (See discussion in section VI.B.2 of this preamble.) We can discern no compelling reason to have separate and potentially inconsistent supervision standards in the exceptions under section 1877 of the Act. Accordingly, the level of supervision required under the physician services exception is the level of supervision required under the payment and coverage rules applicable to the particular physician service at issue.

Second, as noted above, we are expressly interpreting the exception to apply to referrals to (or physician’s services supervised by) a member of the group practice or an independent contractor who qualifies as a “physician in the group” as defined in § 411.351.

Finally, as many have pointed out, the physician services exception (unlike the in-office ancillary services exception) does not cover referred services that are performed by the referring physician. We believe this narrower scope of the physician services exception is evidence that personally performed physician services fall outside the scope of section 1877 of the Act. For this and other reasons expressed elsewhere in this preamble, in § 411.351 of Phase I of this rulemaking, we are defining a “referral” for purposes of section 1877 of the Act to exclude referrals for work personally performed by the referring physician, and we have made clear that a referring physician is not himself or herself an entity to which he or she makes referrals.

Comment: A commenter asked that the regulations include a clear provision for providing compensation for professional reading fees within an outpatient group practice for diagnostic procedures such as EKG, pulmonary function testing, EEG, etc.

Response: To the extent that the professional reading fees mentioned by

the commenter are DHS (see § 411.351), the rules set forth in these regulations apply. (We note, however, that pulmonary function testing and EKGs and ECGs typically will not be DHS unless furnished in a hospital setting.) First, if the professional reading is performed personally by the referring physician, no referral occurs for purposes of section 1877 of the Act (though there may still be a referral of the technical component). Second, if the professional reading is performed by a physician other than the referring physician, the physician services and in-office ancillary services exceptions are available. In the case of a group practice, physician compensation will be governed by the rules in § 411.352 (Group practice). Subject to those rules, the physician performing the professional reading may be paid directly based on his or her personal performance of professional services.

Comment: A commenter expressed the view that all physician services are excluded from the scope of section 1877 of the Act. The commenter asserted that no evidence exists that the Congress intended to include in section 1877 of the Act physician services within the meaning of section 1861(s)(1) of the Act. The commenter, therefore, concluded that including professional components of services is beyond the scope of section 1877 and our regulatory authority.

Response: We disagree. A number of the DHS enumerated by the Congress in section 1877(h)(6) of the Act include substantial physician services components, and the Congress provided no exclusion or carve out. Indeed, we believe the physician services exception itself clearly evidences the Congress's recognition that the DHS categories set forth in section 1877(h)(6) of the Act include some physician services. At the very least, the Congress anticipated that there might be situations in which it would be difficult to demarcate clearly professional and technical components of the DHS. For those situations, the Congress provided an exception that makes clear that group practice physicians may refer physician services within their group practices when the conditions of the exception are satisfied.

Comment: A commenter inquired whether the physician services exception applies to services performed by a nonphysician. In the commenter's view, if the exception does not apply to these services, the exception would conflict directly with our other rules on the practice parameters applicable to nonphysician practitioners.

Response: We are cognizant of the expanding and evolving role of

nonphysician practitioners in the health care delivery system for Medicare beneficiaries. Notwithstanding, we are not persuaded that an expansion of the physicians' services exception is appropriate or, in the light of other interpretations set forth in these regulations, necessary to accommodate the commenter's concerns.

Section 1877(b)(1) expressly applies only to physicians' services as defined in section 1861(q) of the Act. Section 1861(q) of the Act provides that physician services are "professional services performed by physicians." The Act provides for Medicare coverage for certain services that would be physicians' services if furnished by a physician when such services are performed by a physician assistant (under the supervision of a physician) or a nurse practitioner or clinical nurse specialist (working in collaboration with a physician) (see sections 1861(s)(K)(i) and (s)(K)(ii) of the Act.) However, while such services may be identical to physicians' services, they are not physicians' services under section 1861(q) of the Act. Congress has provided for separate treatment of such services under the payment rules. To define nonphysician services as physician services for purposes of section 1877(b)(1) of the Act would distort Medicare's overall payment and coverage scheme.

We are also concerned that expanding the physicians' services exception, which has no building or billing requirements, to include nonphysician practitioners' services would permit group practices to circumvent the requirements of the in-office ancillary services exception.

However, while we are not including nonphysician services under section 1877(b)(1) of the Act, we have made other changes in the regulations that address the commenter's concerns. Specifically, we have interpreted the direct supervision requirement of the in-office ancillary services exception as requiring the level of supervision mandated under the relevant Medicare payment and coverage rules. See section VII.B.2 of this preamble. In other words, in the case of nonphysician practitioners, the supervision requirement of the in-office ancillary services exception corresponds to the supervision requirements applicable to such practitioners. Thus, the in-office ancillary services exception will cover most referral DHS provided by nonphysician practitioners in a group practice setting (provided the exception's building and billing requirements are also satisfied), without

imposing additional supervision requirements on such practitioners.

Moreover, referrals made by nonphysician practitioners generally do not implicate section 1877 of the Act, which focuses exclusively on referrals by physicians. However, if a referral made by a physician assistant or nurse practitioner (or other nonphysician) is directed or controlled by a physician, we are treating the referral as an indirect referral made by the directing or controlling physician, who is, in fact, the "referring physician." This interpretation is necessary to prevent the use of nonphysician practitioners to circumvent section 1877 of the Act.

We believe these interpretations adequately address the commenter's concerns and are consistent with the statutory language and structure. However, we invite public comments as to the need for a further exception for referred DHS performed by nonphysician practitioners in a group practice setting.

Comment: A commenter sought clarification as to the treatment of "incident to" services under the physicians' services exception. The commenter believed that unless "incident to" services are included in the exception, the exception would conflict with other payment and coverage rules.

Response: We are interpreting the physicians' services exception to apply only to "incident to" services (as defined in § 411.351) that are physician services under section 1861(q). All other "incident to" services would need to qualify under the in-office ancillary services or another exception.

Comment: A commenter suggested that the term "physician" should be defined in the regulations.

Response: The Act defines "physician" in section 1861(r). We agree that it would be helpful to incorporate this definition into these regulations and are doing so.

B. In-office Ancillary Services (Section 1877(b)(2) of the Act)

The Existing Law: We have divided our discussion of the in-office ancillary services exception into four subsections that correspond with the statutory structure: DHS included in the in-office ancillary services exception, supervision, building requirements, and billing requirements. The relevant provisions of the existing law are described in each subsection below.

The Proposed Rule: The relevant provisions of the proposed rule are described in each subsection below.

The Final Rule: Many commenters were highly critical of the January 1998

proposed rule's interpretation of the exception for in-office ancillary services, contending that the rule was arbitrary, inconsistent with our existing policies, and inefficient. We have revisited the premises of the January 1998 proposed rule, reexamined the statutory language and legislative history, and restructured the exception. The in-office ancillary services exception in Phase I of this rulemaking is consistent with the language of section 1877 of the Act and the organization and operation of many modern physicians' offices. While in most respects the exception is broader and administratively simpler than the proposed exception, we have substantially limited the ability of group practices to use part-time arrangements to provide DHS in buildings or facilities in which they do not routinely provide a wide range of services other than Federal or private pay DHS.

In revising the exception, we were cognizant of several key considerations. First, the Congress clearly was concerned with regulating physicians' ordering of DHS, even in the context of their own practices; otherwise, a detailed exception would not have been necessary. Second, the Congress intended to protect some in-office ancillary services provided they were truly ancillary to the medical services being provided by the physician or group; otherwise, the Congress would not have created the exception. Finally, we believe the boundaries of the exception as intended by the Congress are best expressed in the building requirement in section 1877(b)(2)(A)(ii) of the Act, which permits DHS to be provided in the same building where the physicians provide their regular medical services, or, in the case of a group practice, in a central DHS building.

Based on those considerations, we have revised the in-office ancillary services exception to permit the provision of DHS in the same building in which a group or a physician routinely provides the full range of the group's or physician's medical services with a minimum of restrictions. In general, the final exception will protect shared DHS facilities, so long as the physicians or groups that share the facility also routinely provide their full range of services in the same building. Moreover, in certain circumstances, part-time practitioners would be permitted to share the DHS facility, as long as they are also providing medical services they routinely provide that are not DHS (whether Federal or private pay). Coupled with a relaxation of the proposed supervision requirement

described below, we believe the final exception captures what the Congress intended to protect.

What will not be protected by Phase I of this rulemaking are a number of part-time, intermittent arrangements that functionally are nothing more than shared off-site facilities. Many of these part-time, off-site ancillary services arrangements are inconvenient for patients both as to location and time, and are created by physicians principally to capture revenue rather than to enhance patient care. To preclude such arrangements, and as a counter-balance to allowing certain shared facilities, we have interpreted the same building requirement as including a "full range of services" condition, and the centralized building requirement as requiring exclusivity. These interpretations are consistent with the statutory language and structure. To the extent the January 1998 proposed rule would have permitted these arrangements, it is no longer operative. To qualify under the "centralized building" standard, Phase I of this rulemaking will require, among other things, the group practice to own or lease and use the space exclusively on a full-time basis.

In addition to the changes to the "building" requirements, the exception for in-office ancillary services under Phase I of this rulemaking contains a number of other significant changes (all described in more detail in the relevant comments and responses sections that follow):

- Significantly expanding the scope of services potentially included in the in-office ancillary services exception by—(1) making clear that outpatient prescription drugs may be "furnished" in the office, even if they are used by the patient at home; (2) explicitly permitting external ambulatory infusion pumps that are DME to be provided under the in-office ancillary services exception; (3) making clear that chemotherapy infusion drugs may be provided under the in-office ancillary services exception through the administration or dispensing of the drugs to patients in the physician's office; and (4) creating a new exception for certain items of durable medical equipment (DME) furnished in a physician's office for the convenience of the physician's patients.

- Substantially modifying the "direct supervision" requirement to conform it to relevant Medicare and Medicaid payment and coverage rules for the specific service, in keeping with our premise that the Congress did not intend to revamp radically the provision

of ancillary services in physicians' offices.

- Allowing independent contractors to provide the requisite supervision, provided they are "physicians in the group practice," meaning that they have contracted with the group practice to treat group practice patients on group premises and have reassigned their claims to the group under § 424.80 of these regulations (as further explained in section 3060, "Reassignment," of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process).

Additional revisions and modifications to the rule are addressed in the discussion below. The discussion is divided into four subparts: the scope of DHS, supervision, building requirements, and billing requirements. The discussion of each subpart contains summaries of public comments and our responses to them.

1. Scope of Designated Health Services That Can Be In-Office Ancillary Services

The Existing Law: As a threshold matter, the DHS that are potentially protected by the in-office ancillary services exception are any of the DHS enumerated in section 1877(h)(6) of the Act, *except* DHS specifically excluded from the exception under section 1877(b)(2) of the Act. Excluded are all parenteral and enteral nutrients, equipment, and supplies (PEN) and DME (except for infusion pumps, which remain eligible for the exception). Referrals—in-office or otherwise—for services that are not DHS need not fit in the exception, since they do not implicate the statute. The scope of services that are considered to be DHS is discussed in section VIII.A of this preamble.

The Proposed Rule: We proposed that DHS would be considered furnished in the location where the service was actually performed or where a patient receives and begins using an item. We also proposed expanding the category of DHS included in the in-office ancillary services exception to include crutches, provided the physician does not mark up the cost of the crutches.

The Final Rule: First, we are revising the rule to provide that services will be considered "furnished" for purposes of the exception (1) in the location where the service is actually performed upon a patient or (2) when an item is dispensed to a patient in a manner that is sufficient to meet Medicare billing and coverage rules. This change will make application of the rule clearer in the case of outpatient prescription drugs and ambulatory infusion pumps that are DME. Second, in the interests of patient convenience, we are using our

regulatory authority under section 1877(b)(4) of the Act to expand the exception to include certain DME, including crutches, canes, walkers, and folding manual wheelchairs, that meet conditions set forth in the regulations. (Braces and collars are orthotics and, thus, may already qualify under the statute for the in-office ancillary services exception.) These conditions generally will require that—(1) the items are DME, such as canes, crutches, walkers, and folding wheelchairs, that a patient uses to ambulate in order to leave the physician's office; (2) the items are furnished in a building that meets the "same building" requirements of section 1877(b)(2) of the Act and § 411.355(b)(2)(i) as part of the treatment for the specific condition for which the physician-patient encounter occurred; (3) the items must be furnished personally by the physician who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice; (4) the physician who furnishes the DME must meet all DME supplier standards; (5) the arrangement does not violate the anti-kickback statute; (6) the billing and claims submission for the DME complies with all applicable laws and regulations; and (7) all other requirements of the in-office ancillary services exception are satisfied. We are similarly excepting blood glucose monitors.

We are withdrawing our proposal that physicians not mark up these items when provided in-office to their patients; we believe the current DME Regional Carrier (DMERC) reimbursement provisions provide sufficient cost containment controls. We believe these limited modifications to the DME exclusion will promote quality of patient care without any significant increased risk of patient or program abuse.

Finally, with respect to infusion pumps (other than pumps that are PEN equipment or supplies), we are including, under Phase I of this rulemaking, the furnishing of external ambulatory infusion pumps as in-office ancillary services covered by the exception (which uses the generic term "infusion pumps"), provided all other conditions of the exception are satisfied. Because they are specifically included in the statutory exception, external ambulatory infusion pumps need not meet the added requirements for DME outlined in the preceding paragraph.

Comment: A hospital-based pathologist in a hospital with a full-service laboratory urged that the in-office ancillary services exception should not protect laboratories based in

physicians' offices. The pathologist asserted that these laboratories are merely enterprises that enable physicians to profit from referrals for laboratory tests and create unfair competition for pathology laboratories that are not owned by physicians. The pathologist expressed skepticism about the justification proffered by many physicians that in-office laboratories exist for the convenience of patients, noting that, in his case, his hospital laboratory is located directly across the street from the offices of physicians with in-office laboratories.

Response: Despite the fact that physician-owned or controlled laboratories and other DHS facilities may competitively disadvantage entities that do not have physician ownership or control, the Congress made a policy determination not to apply the prohibition under section 1877 of the Act to DHS referrals that occur within the parameters of a physician's or group practices' own medical practice, provided these referrals fit squarely in an exception under section 1877 of the Act.

Comment: The in-office ancillary services exception applies to DHS that are "furnished" in accordance with certain statutory conditions. A number of commenters objected to our interpretation that the term "furnished" excluded items provided to a patient (or delivered to a patient's home) that are meant to be used at home rather than in the physician's office. The commenters observed that such a rule does not make sense in the case of outpatient prescription drugs, which are commonly dispensed to patients for later consumption at home.

Response: In general, we believe the Congress intended to exclude from the reach of the statute only items and services provided (or used, as the case may be) in the physician's office. However, we believe that our definition of those circumstances can be simplified to accommodate the provision of outpatient prescription drugs, as well as ambulatory infusion pumps that are DME. Accordingly, we are revising the rule to provide that services will be considered "furnished," for purposes of the exception, in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the Medicare billing and coverage rules.

Comment: One commenter suggested that we should make clear that so long as the in-office ancillary services exception is met, discounts on drugs do not need to be passed on to Medicare.

Response: Nothing in section 1877 of the Act or these regulations is intended to require physicians to pass discounts on to the Medicare program. Whether a discount must be passed on to the program by physicians or others remains the subject of other statutory and regulatory provisions.

Comment: Commenters requested clarification that the furnishing of chemotherapy drugs can meet the in-office ancillary services exception. Commenters also sought clarification with respect to chemotherapy-related laboratory tests, x-rays, and prescription drugs that are secondary to the provision of chemotherapy.

Response: Chemotherapy infusion drugs and ancillary laboratory tests, x-rays, and prescription drugs are DHS for purposes of section 1877 of the Act that may be provided by physicians as in-office ancillary services if all of the conditions of the exception are satisfied. In light of the changes we are making in Phase I of this rulemaking—including revisions to the definition of "furnish" and to the supervision requirement in § 411.355(b)(5)—we believe the exception is sufficiently broad to accommodate virtually all existing arrangements for the provision of chemotherapy drugs and related services to patients in physicians' offices. Under Phase I of this rulemaking, referrals for chemotherapy infusion drugs may be protected by the in-office ancillary services exception if they are administered or dispensed to patients in the referring physician's office (or through the referring physician's group practice) in accordance with the supervision requirements already imposed by the Medicare program. We anticipate no appreciable disruption of chemotherapy services to Medicare or other patients as a result of Phase I of this rulemaking.

Comment: A commenter sought clarification whether the furnishing of allergen treatment sets would be protected under the in-office ancillary services exception.

Response: The provision of allergen treatment sets is protected by the in-office ancillary services exception so long as all of the conditions of the exception are satisfied. We believe that the changes in Phase I of this rulemaking to the definition of "furnish" in § 411.355(b)(5) and the supervision requirements make clear that allergen treatment sets may be furnished to patients under the in-office ancillary services exception.

Comment: A number of commenters questioned the scope of our proposed extension of the in-office ancillary services exception to include the

furnishing of crutches (DME being otherwise excluded by statute). The proposed extension would permit physicians to provide crutches if they make no profit on them and otherwise meet certain criteria. We proposed that the physician could bill only for the cost of acquiring and supplying the crutches. Commenters were confused as to how these costs would be determined and found the proposal to be unnecessarily restrictive. In addition, commenters wondered why crutches were included, but not canes, walkers, collars, splints, and the like. Other commenters variously sought inclusion of other DME, including DME for rheumatological conditions, orthopedic DME, and blood glucose monitors. Commenters suggested various measures for determining when DME should be permitted as an in-office ancillary service. One commenter proposed that whatever test we adopt should take into account the following: (1) the intended use of the item (that is, whether the item is an integral element in the customary continuum of patient care); (2) the cost of the item (that is, fair market value or a dollar cap); (3) the life-expectancy of the item (that is, whether items are limited to one-time prescriptions for 5 or 6 weeks); and (4) physician instruction (that is, whether some physician instruction in the use of the item is required). Other commenters proposed dollar caps as a means of excluding from the exception physician-directed sales of expensive wheelchairs, beds, and other pieces of equipment on which markups are significant.

Response: In the interest of patient convenience, we are using our regulatory authority under section 1877(b)(4) of the Act to expand the in-office ancillary services exception to include certain DME, including crutches, canes, walkers, and folding wheelchairs, that meet conditions set forth in the regulation (in our January 1998 proposed rule, we proposed a more limited exception for crutches only). (Braces and collars are classified as orthotics and already potentially qualify under the statute for the in-office ancillary services exception; splints are covered under section 1861(s)(5) of the Act and are not included in any category of DHS.) In doing so, we are concerned primarily with enabling the patient to depart from the physician's office. The narrow scope of this expansion and the fact that the need for ambulation equipment is objectively verifiable mitigate the potential for overutilization.

For somewhat different reasons, we are also creating an exception to permit blood glucose monitors (and one starter

set of testing strips and lancets, consisting of no more than 100 of each; this number is at least one month's supply) to be provided under the in-office ancillary services exception (under the authority granted in section 1877(b)(4) of the Act). In light of section 4105 of the BBA 1997, which added a Medicare benefit for diabetes self-management training services, we do not believe that the Congress intended the physician self-referral law to interfere with a physician's efforts to provide blood glucose monitors to patients. Therefore, the in-office ancillary services exception may be used by a physician or group practice to furnish a blood glucose monitor and a starter set of strips and lancets if the physician or group furnishes outpatient diabetes self-management training to patients for whom the blood glucose monitors are furnished.

While commenters sought the inclusion in this exception of various other items of DME, we decline to extend the in-office ancillary services exception further. To do so would, in essence, vitiate the congressional determination to exclude DME from the in-office ancillary services exception. We do not find—and we believe that the Congress did not find—that the in-office furnishing of other DME would pose no risk of fraud or abuse, as required under section 1877(b)(4) of the Act.

Having considered the various suggestions made by the commenters, we are adopting the following conditions for DME provided as an in-office ancillary service (these conditions being in addition to all other conditions of the exception):

- The item is one that a patient requires for the purposes of ambulating, uses in order to depart from the physician's office, or is a blood glucose monitor (including one starter set of test strips and lancets).
- The item is furnished in a building that meets the "same building" requirements in the in-office ancillary services exception as part of the treatment for the specific condition for which the physician-patient encounter occurred.
- The item is furnished personally by the physician who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice.
- A physician or group practice that furnishes the DME meets all DME supplier standards located in paragraph (c) of § 424.57 (Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing numbers).

- The arrangement does not violate the anti-kickback statute or any law or regulation governing billing and claims submission. (This condition is necessary to meet the "no risk of fraud or abuse" standard in 1877(b)(4) of the Act.)

- All other requirements of the in-office ancillary services exception are satisfied.

We agree with the commenters that our proposal with respect to not marking up costs was confusing and unnecessarily restrictive, and we are not adopting it. While we find the commenters' suggestions for dollar caps on DME items attractive, we have concluded that it is not feasible to devise dollar caps that would appropriately include low-value DME and exclude high-value DME in all cases (for example, a \$150 limit might be high for some types of DME and low for others). Upon further reflection, we believe the current DMERC reimbursement provisions provide sufficient cost containment controls, with respect to these items of DME we are including in the exception. We believe the modifications to the DME exclusion that we are making will promote quality of patient care without any significant increased risk of patient or program abuse.

Finally, we note with respect to DME furnished in physicians' offices that these arrangements remain subject to our conditions of participation for DME suppliers and other applicable payment and coverage rules.

Comment: A commenter asked that the final rule address whether the use of consignment closets as a means of providing DME in a physician's office implicates section 1877 of the Act. For example, a surgeon enters into an arrangement for a DME supplier to rent space (for example, a closet) in the surgeon's office at fair market value under a lease that meets the rental exception. The technician who measures for braces or DME supplies is a shared employee of the surgeon's practice and the supplier, with the supplier paying for the time the technician spends measuring the braces and supplying DME. The billing is done by the supplier. The commenter asserted that in this example, there is no financial relationship because the surgeon does not bill Medicare.

Response: If the lease fits squarely in the rental exception and the arrangement for the personal services of the technician fits squarely in the personal service arrangements exception, the "consignment closet" arrangement described in the preceding comment may not create a prohibited financial relationship under section

1877 of the Act. We wish to clarify that this result does not depend on whether the physician bills Medicare. To the contrary, the essential prohibition under section 1877 of the Act is on physicians making referrals to entities with which they have prohibited financial relationships and on those entities billing Medicare. Nothing in this rule is intended to, or should be interpreted as, legitimizing consignment closet arrangements. These arrangements raise significant questions under other legal authorities, including the anti-kickback statute and our supplier standards. Physicians and suppliers who are considering "consignment closet" arrangements would be well-advised to read the OIG's Special Fraud Alert on the Rental of Physician Office Space by Persons or Entities to Which They Refer published in the **Federal Register** on February 24, 2000 (65 FR 9274).

Comment: One commenter expressed concern about the interaction of section 1877 of the Act and the proposed surety bond rule that would exempt physicians from the surety bond requirement if they provide DME incident to patient care. Specifically, the commenter asked whether we believe that physicians are allowed to disburse DME, orthotics, and prosthetics incident to patient care without violating the provisions of section 1877 of the Act and whether these provisions are applicable if a physician has a surety bond.

Response: Section 1877 requirements under the exception exist wholly apart from other requirements of law that may apply. In addition, the commenter is mistaken in asserting that we proposed to exempt physicians who furnish DME in their offices from the proposed surety bond requirements that would apply to all suppliers. We assume that the commenter is referring to our proposed rule concerning supplier standards that was published on January 20, 1998 (63 FR 2926). Such an exception is not included in the proposed rule.

Comment: Oncologists complained that the proposed regulations—which interpreted the in-office ancillary services exception as applying only to infusion pumps that are implanted in a physician's office—would prohibit them from furnishing external ambulatory infusion pumps to their patients, contravening clear congressional intent and causing substantial inconvenience to patients. External ambulatory infusion pumps are used to administer chemotherapy agents and pain medication to cancer patients. The pumps are typically filled in the oncologist's office, and the drug flow is ordinarily initiated before the patient leaves the office. The statutory in-office

ancillary services exception excludes DME (which typically is used by patients in their homes), but includes "infusion pumps." Thus, the commenters asserted that the plain language of the exception indicates clear congressional intent to authorize physicians to furnish a certain category of DME—infusion pumps—to patients, even though those pumps will be used at home.

Response: We agree. The statute uses the general term "infusion pumps." We are revising the regulation in § 411.355(b) to make clear that the in-office ancillary services exception protects external ambulatory infusion pumps (other than pumps that are PEN equipment or supplies) that are filled or serviced in the physician's office, even though the patient uses them at home. However, the in-office ancillary services exception does not protect an infusion pump that is used to deliver PEN because that pump is not classified as DME, but is considered PEN. PEN is categorically excluded from the exception under section 1877(b)(2) of the Act. The statutory language addressing infusion pumps in the in-office ancillary services exception applies only to DME.

Comment: Two commenters requested clarification as to the application of the in-office ancillary services exception to home care physicians who primarily treat patients in their homes. These commenters asserted that home care physicians play an important role in the delivery of cost-effective, quality care to patients and provide services that, in some cases, preclude the need for more expensive hospitalizations. These commenters believe that section 1877 of the Act should not apply to home visits. In the alternative, these commenters requested clarification of the following issues:

- Are DHS performed in a patient's home concurrently with the performance of a physician service included in the in-office ancillary services exception (for example, a physician uses a hand-held portable laboratory during a physician visit in the home)? Can a technician accompanying the physician perform the DHS during the home visit?
- What is the application of section 1877 of the Act to group practices that own home health agencies that in turn provide DHS to group patients?
- Are referrals from medical directors of home health agencies protected by the employee or another exception?

Response: We find nothing in the statute that excludes referrals for DHS by home care physicians from the reach of the statute. To the contrary, the

Congress expressly included home health services as a designated health service. That said, we generally agree with the commenters that the provision of DHS in a patient's home should be protected by the in-office ancillary services exception, provided that all of the conditions of the exception are satisfied. However, in many cases, services provided by home care physicians will not fit neatly into the in-office ancillary services exception. For example, under the "same building" requirements, we are requiring that physicians provide substantial physician services unrelated to DHS in the building and that the services provided there be the full range of the physicians' services. We believe that a home care physician meets these "same building" tests if his or her principal medical practice consists of treating patients in their private homes (for purposes of determining whether a physician is principally a home care physician, private homes do not include nursing, long term care, or other facilities), and the physician (or a staff member accompanying him or her) provides a designated health service in a private home contemporaneously with a physician service (provided by the referring physician) that is not a designated health service and the other exception requirements are met. (DHS provided in facilities, such as nursing homes, by home care or other physicians may qualify under the in-office ancillary services exception if all conditions of the exception are satisfied.) We have concluded that it may be appropriate to develop additional rules for home care physicians under the in-office ancillary services exception. We are expressly soliciting comments on this issue and will consider it further in Phase II of this rulemaking.

As to the commenter's second question, section 1877 of the Act applies to a group practice's ownership of a home health agency in the same manner it applies to the ownership by a group practice of any DHS entity. Referrals to the entity by the group practice or by members of the group must qualify under an ownership exception, such as the in-office ancillary services exception. In general, we do not believe that the furnishing of most home health services will meet the requirements of the in-office ancillary services exception. Unless a physician in the group personally conducts the home visit and provides a physician service unrelated to the furnishing of DHS, the "same building" requirements will not be satisfied (we see no plausible way for

home health services to qualify under the “centralized building” option under section 1877(b)(2)(A)(ii)(II) of the Act). In some cases, the “rural provider” exception may apply (that exception will be discussed in the Phase II rulemaking).

Finally, with respect to referrals from medical directors of home health agencies, these referrals may be protected by the employee exception or the personal service arrangements exception, depending on the facts and circumstances of the medical director’s relationship with the home health agency. However, if the medical director is an owner of a group practice that owns the home health agency, an ownership exception would still need to apply.

Comment: A commenter sought clarification as to whether a referral to a physician spouse in another group practice, who subsequently orders a designated health service for the referred patient, could come within the in-office ancillary services exception. The commenter observed that there are many two-physician marriages in the health care industry and that many spouses engage in different specialties and practice in different group practices. The commenter argued that the referrals between physician spouses to each other’s group practices should not constitute prohibited referrals, so long as either the referring physician or the physician spouse accepting the referral complies with an exception. In our January 1998 proposed rule, we took the position that a physician in one group practice will be prohibited from referring to his or her physician spouse in another group practice because the referring physician cannot meet the in-office ancillary services exception. The commenter found this interpretation overly restrictive and narrow. In the commenter’s view, if the physician receiving the referral meets the in-office ancillary services exception, he or she should be able to accept the referral, because the accepting spouse and not the referring spouse is ordering the designated health service.

Response: On reconsideration, we generally agree with the commenter, with one important distinction. We believe that the referral to a spouse should be allowed, if the referral is for a physician service unrelated to the furnishing of a designated health service (that is, a designated health service is not the reason for the referral) and any subsequent DHS referrals by the spouse fit within the in-office ancillary services exception with respect to the spouse receiving the referral. We recognize that there may be some circumstances,

particularly in underserved areas, where a spouse may be the *only* qualified provider of a particular DHS. We are considering whether a limited additional exception is warranted and will address the issue further in Phase II of this rulemaking. We invite comments on this issue.

2. Direct Supervision

The Existing Law: Section 1877(b)(2) of the Act provides an exception for in-office ancillary services. To qualify as in-office ancillary services, the services must, among other things, be furnished personally by a referring physician or another physician member in the same group practice, or be furnished by individuals who are “directly supervised” by the referring physician or another physician in the group practice. The August 1995 final rule covering referrals for clinical laboratory services defined “direct supervision” in § 411.351 as supervision by a physician who is present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed.

The Proposed Rule: The January 1998 proposed rule retained this definition, with several clarifications and changes. In the preamble to the January 1998 proposed regulation, we expressed our view that the Congress intended the in-office ancillary services exception to apply to services that are closely attached to the activities of the referring physician. Consistent with this interpretation, we used the definition of “direct supervision” that appears in section 2050, “Services and Supplies,” of the Medicare Carriers Manual (HCFA Pub. 14–3), Part 3—Claims Process, which describes services that are incident to a physician’s professional services under section 1861(s)(2)(A) of the Act. Under this rule, supervision must be provided by a physician who is present in the office suite in which the services are being furnished, throughout the time they are being furnished, and who is immediately available to provide assistance and direction. The definition in the proposed rule also clarified the meaning of the term “present in the office suite” to mean that the physician is actually physically present. However, we would still have considered the physician “present” during brief unexpected absences, as well as during routine absences of a short duration (such as during a lunch break), provided the absences occur during time periods in which the physician is otherwise scheduled and ordinarily expected to be present and the absences do not conflict with any other requirements in the

Medicare program for a particular level of physician supervision.

The Final Rule: Our interpretation of the “direct supervision” standard produced the largest number of public comments about the in-office ancillary services exception, virtually all suggesting that our proposal would be overly burdensome, result in enigmatic technical rules, and require wasteful and inefficient practices.

We have revisited the direct supervision requirement and are now interpreting “directly supervised” in the statute to mean that the supervision meets the supervision requirements under applicable Medicare and Medicaid payment or coverage rules for the specific services at issue. Upon further review and consideration, we concluded that the Congress did not use the phrase “directly supervised” in any technical sense. Rather, the Congress sought to establish a nexus between the referring physician and the individual performing the ancillary services in order to limit the exception to services that are truly “ancillary” to the referring physician’s medical practice. We believe that the Congress did not intend section 1877 of the Act to supersede or replicate existing statutory and regulatory structures that address supervision of services from the perspective of quality of care or patient safety. This interpretation is consistent with the often cited legislative history for section 1877 of the Act indicating that the Congress did not intend to require physicians to be present at all times that ancillary services were being performed. (See Conference Report for OBRA 1993, H. Rep. No. 213, 103d Congress 810 (1993).) Instead, we believe a sensible approach is to defer to existing Medicare and Medicaid supervision requirements. (Those rules are not addressed in Phase I of this rulemaking.)

In our January 1998 proposed rule with respect to the group practice definition, we proposed eliminating independent contractors as members of the group practice. This created the prospect that independent contractors would not be able to provide the supervision required under the in-office ancillary services exception. The statute provides that physicians “in the group practice” may supervise the furnishing of ancillary services to patients of a referring physician who is a member of the group practice. Under Phase I of this rulemaking, physicians “in the group practice” include owners of the group practice, employees of the group practice, and independent contractors who are “in the group practice.” Owners and employees may also be

members of the group; independent contractors may not. We will consider an independent contractor physician to be "in the group practice" if he or she has a contractual arrangement to provide services to the group's patients in the group practice's facilities and the independent contractor's arrangement with the group complies with the reassignment rules in § 424.80(b)(3) of these regulations and in section 3060.3, "Payment to Health Care Delivery System," of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process. Independent contractors who qualify as physicians "in the group practice" may receive overall profit shares and productivity bonuses described in section 1877(h)(4)(B)(i) of the Act, as implemented by these regulations, and may provide the supervision required under the in-office ancillary services exception.

Comment: Many commenters raised concerns about the level of supervision required under the in-office ancillary services exception. Many commenters objected to our proposed interpretation of the direct supervision requirement, which would have adopted the supervision requirement applicable to "incident to" services in section 2050, "Services and Supplies," of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process, including a "present in the office suite" requirement, with an exception for brief absences by the physician. These commenters variously found the "presence" requirement overly burdensome, impractical, confusing, and unclear. Commenters believe that a general requirement of a physician's physical presence for all ancillary services would create unnecessary inefficiencies in the delivery of health care services, drive up costs, and inconvenience patients. For example, some commenters noted that tests are often scheduled in the mornings when physicians are making rounds or attending hospital meetings, with the physicians interpreting the tests when they arrive later at the office. Some commenters observed that they could discern no obvious connection between direct supervision and curtailing fraud and abuse. Others noted that a strict direct supervision requirement does not guarantee that DHS are medically appropriate and are not simply being performed for financial gain.

Commenters suggested various alternative standards, including "appropriate supervision," "professional responsibility," "general supervision," and "employee status." The vast majority of commenters, however, urged that the in-office

ancillary services exception "direct supervision" requirement be interpreted to comport with the applicable supervision requirements under our other payment and coverage rules. These commenters stressed that these rules adequately take into account quality concerns and the health and safety of patients and that there is no justification for imposing an additional layer of supervision requirements.

Response: Upon further review and consideration of the statute, the legislative history, and the public comments, we have concluded that the Congress did not use the phrase "directly supervised" in any technical sense in the statute. Rather, we believe the Congress sought to establish a nexus between the referring physician and the individual performing the ancillary services in order to limit the exception to services that are truly "ancillary" to the referring physician's medical practice. We believe that the Congress did not intend section 1877 of the Act to supersede or replicate existing statutory and regulatory structures that address supervision of services from the perspective of quality of care or patient safety. This interpretation is consistent with the often cited legislative history indicating that the Congress did not intend in the context of section 1877 of the Act to require physicians to be present at all times that ancillary services were being performed ("The conferees intend that the requirement for direct supervision by a physician would be met if the lab is in the physician's office which is personally supervised by a lab director, or a physician, even if the physician is not always on site" (H. Rep. No. 213, 103d Cong. 810 (1993)). We are persuaded that a more sensible approach is to defer to existing Medicare and Medicaid supervision requirements. (Those rules are not addressed in Phase I of this rulemaking.) Thus, the in-office ancillary services exception supervision requirements will be satisfied if the level of supervision provided meets all applicable Medicare or Medicaid payment and coverage requirements.

Comment: One commenter viewed the strict "direct supervision" standard established in the August 1995 final rule as an important check on inappropriate referrals and objected to any liberalization of the requirement, arguing that it would allow the connection between a physician's activities and DHS to "grow too thin." The commenter believes it is appropriate for us to impose higher standards of care to protect patients who are referred for DHS, because these services have been determined to

present a particularly high risk of inappropriate referrals. The commenter further noted that as the health and safety rationale for supervision declines (supervision being less necessary for certain low-risk services), the risk of unnecessary referrals and overutilization increases. The commenter recommended that we retain the "incident to" direct supervision standard. In the alternative, the commenter proposed a "sphere of service" test under which a physician would be allowed to refer a patient for services only if that physician, and not another licensed practitioner, normally would perform the services. According to the commenter, this approach would eliminate physician incentives to establish "backroom" practices to provide services that could be provided more efficiently elsewhere.

Response: We share this commenter's concerns about inappropriate financial incentives driving the provision of DHS. We are concerned that heightened downward pressure on physician incomes will generate increased upward pressure to expand in-office ancillary services as a means of offsetting income losses. However, we believe the Congress clearly articulated a policy determination to allow in-office ancillary services that meet certain statutory criteria. While the stricter "incident to" supervision standard might serve to reduce the risk of overutilization somewhat, on balance, we believe that using section 1877 of the Act to superimpose a separate supervision requirement on existing regulatory structures governing appropriate levels of supervision would be overly burdensome, inefficient, and inconsistent with the overall design of the statute. We note, however, that physicians wishing to bill DHS "incident to" (and group practice physicians wishing to obtain productivity bonuses for services incident to their personally performed physician services) must comply with the "incident to" supervision requirements, including the "present and available" requirement and the employee requirement, as set forth in section 2050, "Services and Supplies," of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process.

Comment: One commenter asked whether technicians must be directly supervised if a group practice provides technician services to a hospital. If so, the commenter requested that we clarify whether the group practice must follow self-referral supervision standards or hospital supervision standards.

Response: If a hospital is billing for the services, as this commenter implied,

the in-office ancillary services exception does not apply (along with its supervision requirement). Any hospital standards would always apply, since any requirement for supervision under section 1877 of the Act is separate and distinct from other supervision requirements under the Medicare and Medicaid statute and regulations.

Comment: While many commenters approved of our proposal to exclude independent contractors as members of a group practice for purposes of complying with the definitional tests for a group practice (making it easier for many groups, especially smaller groups, to qualify as a group practice for purposes of section 1877 of the Act), many commenters also urged that independent contractors be included as members of a group practice for purposes of the direct supervision requirement of the in-office ancillary services exception. Many commenters expressed concern that our bar on direct supervision by independent contractors would undercut the ability of group practices to deliver necessary health care services in situations in which employment of the physician is not possible or desirable. To support their claim that the statute does not require that the direct supervision be provided by a "member" of the group, commenters observed that section 1877(b)(2)(A)(i) of the Act only requires supervision "by the [referring] physician or by another physician *in the group*." One commenter noted that this language is consistent with section 3060.3, "Payment to the Health Care Delivery System," of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process, which treats independent contractors as "in the group" for reassignment purposes. Another commenter suggested that an independent contractor could properly be considered "in the group" if the physician provides services to the group practice's patients in the group practice's facility under a contract with the group, and the services are billed by the group.

Response: Having reviewed the comments and reconsidered the statutory language, we are persuaded that independent contractors may be physicians "in the group" for purposes of the in-office ancillary services exception. We are considering an independent contractor physician to be "in the group practice" if (1) he or she has a contractual arrangement to provide services to the group's patients in the group practice's facilities, (2) the contract contains compensation terms that are the same as those that apply to group members under section

1877(h)(4)(iv) of the Act or the contract fits in the personal services exception, and (3) the contract complies with the reassignment rules at § 424.80(b)(3) of these regulations and in section 3060.3, "Payment to the Health Care Delivery System," of the Medicare Carriers Manual (HCFA Pub. 14-3), Part 3—Claims Process, so that his or her services are billed by the group practice. We are codifying this new test in § 411.351 of the regulations. This latter requirement presents a technical problem under the plain language of the statute, which we address as follows. The billing requirements under section 1877(b)(2)(B) of the Act do not provide for billing by the group practice when a supervising physician is "a physician in the group practice," rather than a member of the group. Given the statutory structure and language, particularly the language of the direct supervision requirement under section 1877(b)(2)(A)(i) of the Act, we are interpreting the billing requirements to extend to billing by the group practice when the supervising physician is "in the group practice" in order to effectuate the direct supervision requirement. Independent contractors who qualify as "physicians in the group practice" may receive overall profit shares and productivity bonuses described in section 1877(h)(4)(B)(i) of the Act, as implemented by these regulations. As discussed in section VI.C.3 of this preamble, independent contractors are not "members" of the group.

Comment: Several commenters sought clarification with respect to the application of the in-office ancillary services exception to referrals for DHS from an independent contractor to the group practice with which he or she contracts (for example, referrals from an independent contractor to the group's in-office laboratory).

Response: Independent contractor physicians will have compensation relationships with the group practices with which they contract. In order for an independent contractor to refer DHS to the group practice, an exception must apply. Possible exceptions, depending on the circumstances, include the in-office ancillary services exception for independent contractors who are "physicians in the group", the physicians' services exception, the personal service arrangements exception, or the risk-sharing exception for services provided to certain managed care enrollees. We note that under the in-office ancillary services exception, the furnishing of DHS would have to take place in a "same building" location under section 1877(b)(2)(A)(ii)(I) of the

Act, as the "centralized building" provision (section 1877(b)(2)(A)(ii)(II) of the Act) only applies to referring physicians who are group members.

Comment: Several practitioners of ultrasonography commented that a direct supervision requirement that mandates physician presence for in-office ancillaries unfairly benefits radiologists, who are generally available on-site because they do not have "patients" to see or other responsibilities, while disadvantaging vascular laboratories that operate without physicians on-site. The commenters suggested that the rule require that ultrasound examinations and interpretations be performed in accordance with standards set by independent professional associations. However, another commenter—radiologist—urged us to retain the direct supervision requirement in the interest of patient health and safety.

Response: As noted above, we are modifying the direct supervision requirement under the in-office ancillary services exception to apply the requisite supervision requirements under Medicare and Medicaid payment and coverage rules.

3. The Building Requirements

The Existing Law: Under section 1877(b)(2)(A)(ii) of the Act, in-office ancillary services must be furnished in a building in which the referring physician, or another physician who is a member of the same group practice, furnishes physician services unrelated to the furnishing of DHS. Alternatively, in the case of a referring physician who is a member of a group practice, the in-office ancillary services can be furnished in another building that is used by the group practice for the provision of some or all of the group's clinical laboratory services, or for the centralized provision of the group's DHS (other than clinical laboratory services). (The existing regulations address the same and other building requirements only with respect to clinical laboratory services.)

The Proposed Rule: In our January 1998 proposed rule, we proposed defining the "same building" in § 411.355(b)(2)(i) as the same physical structure, with one address, and not multiple structures connected by tunnels or walkways.

The Final Rule: The building requirements are designed to ensure that the DHS qualifying for the exception are truly "in-office" (that is, part of the physician's routine medical office practice) and not provided as part of a separate business enterprise. The location requirements do not pertain to

the furnishing of DHS that are not payable by Medicare or Medicaid; these services may be furnished anywhere, subject to any restrictions in other applicable Federal, State, or local laws.

In general, the structure of the statutory language suggests that the Congress had two main objectives: permitting the provision of in-office ancillary services for the convenience of patients during their patient visits and, in the group practice context, permitting the provision of in-office ancillary services in a dedicated building used for these services (for example, a central clinical laboratory). By contrast, we believe the Congress did not intend to protect part-time rentals of ancillary services facilities under this exception.

Upon further consideration, we believe that the Congress did not intend the application of the in-office ancillary services exception to turn on the nuances of architectural design. Thus, for purposes of Phase I of this rulemaking, a "building" is defined as a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service. For purposes of this rule, the "same building" does not include exterior spaces, such as courtyards, lawns, driveways, or parking lots, or interior parking garages. The building could include a SNF or other facility or a patient's home, provided all other conditions of the exception are satisfied. A mobile van or trailer is not a building or a part of a building.

The statute implements congressional intent by offering two location options: the "same building" option, available to solo practitioners and group practices, and the "centralized building" option, available only to groups. (See section 1877(b)(2)(A)(ii)(I) and (b)(2)(A)(ii)(II) of the Act.)

"Same Building"

Under section 1877(b)(2)(A)(ii)(I) of the Act, services qualify for the in-office ancillary services exception if they are furnished "in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physician services unrelated to the furnishing of designated health services." We believe the underlying intent of this provision is to allow physicians to furnish DHS that are ancillary to the physician's core medical practice in the location where the core medical services are routinely delivered. We believe the Congress did not intend to permit the wholesale provision of DHS in locations in which physicians perform only token services that are not related to the furnishing of DHS (that is, only token physician

services that are not Federal or private pay DHS). Simply stated, the DHS should be ancillary to physician services that are not DHS, and not the other way around. The exception was intended as an accommodation to physicians' customary practice of medicine and not as a loophole for physicians and group practices to operate DHS enterprises that are unconnected—or only marginally connected—to their medical practices. In addition, the significant easing of the "direct supervision" requirement described above necessitates a somewhat stricter interpretation of the location standards than we proposed in our January 1998 proposed rule, in order to ensure an adequate nexus between in-office ancillary DHS and the physician's core medical practice. Thus, we are making the following changes (except where noted) in the "same building" requirements:

- In our January 1998 proposed rule, we proposed interpreting the rule as allowing any quantity of services unrelated to DHS to be furnished in the same building. We are revising the rule to require that the referring physician (or another physician who is a member of the same group practice) must furnish in the same building *substantial* physician services unrelated to the furnishing of Federal or private pay DHS. We are defining the phrase "services unrelated to the furnishing of designated health services" to mean physician services that are neither Federal nor private pay DHS, even if the physician service leads to the ordering of DHS. In addition, to preclude single-service DHS enterprises from the in-office ancillary services exception, we are requiring that the unrelated physician services furnished in the building represent substantially the full range of physician services unrelated to the furnishing of DHS that the physician routinely provides (or, in the case of a member of a group practice, the full range of physician services that the physician routinely provides for the group practice).

- We are adding a requirement that the DHS furnished in the building be furnished to patients whose primary nexus with the referring physician (or his or her group practice) is the receipt of physician services unrelated to the furnishing of DHS. Simply stated, obtaining DHS should not be the main reason the patient has contact with the referring physician (or his or her group practice). Again, this standard will ensure that self-referred DHS are ancillary and not primary services for the patients who receive them. Thus, for example, a physician who provides

physician services and DHS for his or her patients in a nursing home may not also provide token physician services to other nursing home patients in order to provide DHS under the in-office ancillary services exception.

- The space in the building in which the DHS are provided need not be adjacent to the space in which services that are not DHS are provided (subject to the dictates of any Medicare or Medicaid payment or coverage supervision rules).

- Shared facilities in the same building are permitted to the extent they comply with the supervision, location, and billing requirements of the in-office ancillary services exception; we are not, however, creating a broader shared-facility exception.

- We believe that a home care physician whose principal medical practice consists of treating patients in their private homes meets the "same building" requirements if the physician (or a staff member accompanying the physician) provides a designated health service contemporaneously with a physician service (provided by the referring physician) that is not a designated health service in the patient's private home and the other exception requirements are met. Because the location requirements of the in-office ancillary services exception may disadvantage home care physicians, we are considering whether special rules should be developed under the "same building" requirements for physicians who primarily practice as home care physicians. We are soliciting comments on that issue and intend to address it further in Phase II of this rulemaking.

"Centralized Building"

Under section 1877(b)(2)(A)(ii)(II) of the Act, in the case of a referring physician who is a member of a group practice, services qualify for the in-office ancillary services exception if they are furnished "in another building which is used by the group practice * * * for the provision of some or all of the group's clinical laboratory services, or * * * for the centralized provision of the group's designated health services (other than clinical laboratory services)." We believe that this statutory provision—which allows group practices to have "off-site" DHS locations—was intended to accommodate the concerns of group practices with multiple office locations that wanted to consolidate DHS operations for cost containment purposes. However, in permitting group practices to provide centralized DHS, the Congress did not intend to

eviscerate the “in-office” element of the exception. We are therefore interpreting the “centralized building” standard as follows:

- The space (whether an entire building, subpart of a building, or mobile unit) used for the provision of the group practice’s clinical laboratory services or centralized DHS qualifies for the exception only if it is used *exclusively* by the group, that is, it is wholly owned by the group practice or leased by the group practice on a full-time basis (that is, 24 hours per day, 7 days per week). To preclude part-time arrangements in the form of one-day rentals, we are requiring that the centralized building be owned or leased exclusively by the group practice for at least 6 months. This rule precludes facilities shared by group practices in off-site buildings.

- Part-time “centralized” DHS arrangements are precluded. For example, a group practice may not rent a magnetic resonance imaging (MRI) facility 1 day per week and treat that facility as a “centralized” building under section 1877(b)(2)(A)(ii)(II) of the Act.

- Under the authority granted to the Secretary in the unnumbered paragraph that follows section 1877(b)(2)(A)(ii)(II)(bb) of the Act (that allows the Secretary to determine other terms and conditions related to section 1877(b)(2)(A)(ii)(II)(bb) under which the provision of DHS does not present a risk of program or patient abuse), we are determining that a mobile facility (for example, an x-ray van) owned and used *exclusively* by a group practice (24 hours per day, 7 days per week, for at least six months) will be considered to meet the “centralized building” standard, even though a mobile facility is not a building.

- Group practices may lease or sublease DHS facility space (including mobile units) to or from other group practices or solo practitioners on a part-time basis, but DHS provided to patients of part-time lessee or sublessee group practices will not fit in the in-office ancillary services exception, unless the “same building” requirements are met.

- Referrals for ancillary services from other physicians or group practices that are not affiliated with the group practice providing the DHS do not implicate section 1877 of the Act, provided there are no impermissible financial relationships between the parties. A referral for a designated health service does not create a financial relationship.

These building rules are designed to give physicians and group practices a meaningful opportunity to provide *bona fide* in-office ancillary DHS to their

patients, while preventing group practices from using the in-office ancillary services exception to operate enterprises that are functionally nothing more than self-referred DHS enterprises, providing minimal services that are not DHS so as to comply nominally with the exception and capture DHS profits. We believe the Congress did not intend the exception to include these operations. Far from promoting patient convenience and quality of care, these arrangements pose a significant risk of overutilization of services and shuttling of patients to DHS locations for the economic betterment of the physicians, without regard to the patient’s best interests.

Comment: Many commenters found the proposed regulations and interpretations of the “building” requirements to be confusing, over broad, potentially contradictory, and, in the words of one commenter, “metaphysical.” With respect to our proposed “physical structure” requirements, many commenters urged us not to place the agency or physicians into surveying real estate to determine whether a structure is one building. Commenters variously observed that while some walkways or tunnels between commercial medical office buildings may be sidewalks between distinct and separate buildings, other walkways or tunnels are part of the modern architecture of these buildings or are required to comply with zoning, land use, open space, or other real estate laws or to surmount natural barriers present on the site of the building.

There were a number of suggestions for revising the requirement. One group of commenters urged us to adopt a mailing address rule stating that a building would be considered as one building for all suites or room numbers located inside that are required by the U.S. Postal Service to use the same street address, regardless of suite number. Under this rule, suites operated by the same group practice or solo physician in buildings that use separate street addresses would be treated as separate buildings for the purposes of the in-office ancillary services exception. Other commenters objected to a street address test, noting that physicians have no control over the manner in which their buildings are assigned street addresses and that the parameters for assigning street addresses may vary by State and locality. One commenter expressed concern about buildings located on corner lots that might have two street addresses.

A second approach proposed by one commenter was to revise the regulations to allow connected buildings or portions of buildings that are owned or

controlled by the same group practice. Still other commenters claimed that the emphasis should be on the proximity of the supervising physician to the patient during the performance of DHS. Under this view, the location requirement of the in-office ancillary services exception should focus on whether the physician is “immediately available” to the support personnel and not on an artificially imposed physical design constraint. Along these lines, several commenters proposed that services be considered in the “same building” if the physician is within a certain number of minutes (for example, 10 minutes) from the patient or if the physician is “close at hand.”

Response: We regard the building requirement of the in-office ancillary services exception, in combination with the supervision and billing requirements, as the Congress’s attempt to circumscribe the exception so that it applies only to services provided within the referring physician’s actual sphere of practice. Without these requirements, physicians could refer to, and profit from, almost any entity, with the claim that somehow the referred services are “in-office” services that are being supervised from some remote place.

Notwithstanding, we realize that our proposed definition of a “building”—which attempted to define a building in architectural terms—could cause practical problems for some physicians and that a clearer, “bright line” rule would be preferable. Accordingly, having considered the various alternatives suggested by the commenters, we have concluded that for purposes of Phase I of this rulemaking, we are defining a “building” as a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service. A building will be considered as one building for all suites or room numbers located inside that are required by the U.S. Postal Service to use the same street address, regardless of the suite number. Under this rule, suites used by the same group practice or solo physician in buildings with separate street addresses will be treated as separate buildings for the purposes of the in-office ancillary services exception. While we recognize that this mailing address rule may result in an occasional anomaly, we are persuaded that it creates a “bright line” rule that will be easy to apply and will produce fair results in the vast majority of cases. Questionable cases may be appropriate candidates for an advisory opinion.

The space in the building in which the DHS are provided need not be adjacent to the space in which services

that are not DHS are provided (subject to the dictates of any Medicare or Medicaid payment or coverage supervision rules). Shared facilities in the same building are permitted under section 1877 of the Act to the extent they comply with the supervision, location, and billing requirements of the in-office ancillary services exception; we are not creating a broader shared facility exception.

Because of the increased risk of abuse, we do not intend to protect DHS provided by mobile vans or other mobile facilities under the in-office ancillary services exception, except in very limited circumstances described in section VI.B.3 of this preamble. Thus, we wish to make clear that for purposes of this rule, a "building" does not include exterior spaces, such as courtyards or parking lots, nor does it include interior parking garages. For purposes of the in-office ancillary services exception, a building consists of usable professional office space and common areas such as lobbies, corridors, elevator banks, and restrooms.

In light of the changes we are making in the supervision standard, we believe it is necessary to revisit the building standards in order to effectuate congressional intent to limit the scope of the in-office ancillary services exception to services that are truly ancillary to physician services and are not a primary business of the practice. Thus, we are revising the "same building" requirements to more definitively tie in-office ancillary services to the referring physician's core medical practice. Simply stated, we want to ensure that services covered by the exception are, in fact, furnished "in office." Under section 1877(b)(2)(A)(ii)(I) of the Act, services qualify for the in-office ancillary services exception if they are furnished "in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of designated health services." We believe the underlying intent of this provision is to allow physicians to furnish DHS that are ancillary to the physician's core medical practice in the location where the core medical practice occurs. We believe the Congress did not intend to permit the wholesale provision of DHS in locations in which physicians perform only token services unrelated to the furnishing of DHS. Thus, we are interpreting the "same building" requirements as follows:

- The referring physician (or another physician who is a member of the same group practice) must furnish in the same

building *substantial* physician services unrelated to the furnishing of DHS. In addition, we are requiring that the unrelated physician services furnished in the building represent substantially the full range of physician services unrelated to the furnishing of DHS that the physician routinely provides (or, in the case of a member of a group practice, the full range of physician services that the physician routinely provides for the group practice). Independent contractors are not members of a group practice for purposes of section 1877 of the Act; thus, their activities do not count for purposes of compliance with the substantial physician services test or the full range of services test under the "same building" requirements, unless they are the referring physician. (See discussion in section VI.B.3 of this preamble.)

- For purposes of this exception, we are defining the phrase "services unrelated to the furnishing of designated health services" to mean physician services that are neither Federal nor private pay DHS, even if the services might generate orders or referrals of DHS. Thus, for example, a cardiologist who examines a patient and thereafter orders a diagnostic radiology test has performed a service unrelated to the furnishing of DHS. On the other hand, a cardiologist who reads the results of a diagnostic radiology test (such as, for example, a transthoracic echocardiography for congenital cardiac anomalies, CPT code 93303) (whether for a Federal or private pay patient) has performed a service that is related to the furnishing of DHS.

- The DHS furnished in the building are furnished to patients whose primary nexus with the referring physician (or the group practice of which the referring physician is a member) is the receipt of physician services unrelated to the furnishing of DHS. Thus, for example, a physician who provides physician services and DHS for his or her patients in a nursing home may not also provide token physician services to other nursing home patients in order to provide those services under the in-office ancillary services exception.

Comment: One commenter believes that our proposed interpretation of the "same building" requirements contradicts the purpose of section 1877(b)(2)(A)(ii) of the Act. The commenter focused on the part of this provision that requires that ancillary services be furnished in a building "in which the referring physician * * * furnishes physicians' services unrelated to the furnishing of designated health services." The proposed rule regarded a

physician's examination and diagnosis of a patient that leads to the physician requesting a designated health service as acts that are "unrelated to the furnishing of designated health services." The commenter is concerned that this interpretation would allow a physician's office to be a single specialty "mill" in which the physician could quickly generate a large quantity of referrals for profit. In other words, the exception could apply to a physician who does little more than conduct cursory evaluations and refer patients for a particular designated health service (for example, physical therapy). The commenter believes that, instead, the physician's office is meant to be a location in which the physician provides *bona fide* diagnostic and curative services to individuals presenting a variety of conditions.

Response: We share the commenter's general concern about inappropriate DHS arrangements, although we believe that the statute does not require us to include in the in-office ancillary services exception only services referred by physicians who treat a variety of conditions. The focus of the exception, in our view, is the requirement that the services be provided or performed in conjunction with a physician's own professional activities or as adjuncts to physician services, in a location in which the physician (or a member of his or her group practice) practices. If we were to limit this exception as the commenter suggested, some physician specialists might be prohibited from referring within their own practices. On the other hand, we agree that some restriction in the definition is appropriate to preclude physicians from providing virtually nothing more than referrals for DHS. Thus, as discussed above, in Phase I of this rulemaking, we are requiring that the unrelated physician services furnished in the building represent substantially the full range of physician services unrelated to the furnishing of DHS that the physician routinely provides (or, in the case of a member of a group practice, the full range of physician services that the physician routinely provides for the group practice).

Comment: Several commenters believe that our proposal to have our regional carriers determine whether the building requirements are satisfied was unworkable and impractical and would result in inequitable application of the law. Commenters noted that local carriers are often reluctant to express opinions on these issues and disinclined to provide written opinions. If the proposal survives, one commenter urged us, at a minimum, to give carriers

explicit authority and direction to issue these written opinions.

Response: We have endeavored to develop regulations that provide sufficiently clear rules so that parties can determine compliance without resorting to a regional carrier's determination.

Comment: A commenter expressed concern about DHS performed by physicians who travel to see patients. The commenter is a physician in a group practice of six physiatrists who perform electromyography and nerve conduction studies in a midwestern State. The group travels to rural counties in the State in which it practices to evaluate patients for musculoskeletal and neurologic problems. The patients often need nerve testing, and the group's physiatrists are often the only health care professionals in the county able to perform this testing. The commenter expressed concern that the regulations would prohibit the physiatrists from providing needed medical assessment and care to patients in these circumstances.

Response: Electromyography and nerve conduction studies are not physical therapy services under our definition in § 411.351; therefore, referrals for these services do not implicate section 1877 of the Act. Nonetheless, we wish to address the commenter's underlying question regarding traveling practitioners. Assuming that the physiatrist group meets the definition of a group practice under section 1877(h)(4) of the Act and the DHS are performed in the same building where the physiatrist (or a member of the group) also performs substantial physician services unrelated to the furnishing of Federal or private pay DHS, we believe the in-office ancillary services exception may apply in the situation described by the commenter. As noted elsewhere, we are soliciting comments on problems faced by physicians who principally practice in patients' homes and may be disadvantaged by the location requirements of the in-office ancillary services exception. We note also that the rural provider exception (to be addressed in Phase II of this rulemaking) may apply in the situation described by the commenter.

Comment: A commenter asked that we make clear that if a solo practitioner provides a designated health service for his or her own patients in the solo practitioner's own office, then the solo practitioner is not in violation of section 1877 of the Act.

Response: In the vast majority of situations we can envision, if a solo practitioner provides a designated

health service for his or her own patients in the solo practitioner's own office, then the solo practitioner will not violate section 1877 of the Act. First, we are revising the definition of a "referral" for purposes of section 1877 of the Act to exclude DHS personally performed by the referring physician. Second, with respect to DHS performed by employees of the solo practitioner (including "incident to" services), we believe the Congress intended for the in-office ancillary services exception to apply to solo practitioners as well as group practices. Thus, so long as a solo practitioner's provision of DHS meets the in-office ancillary services exception, section 1877 of the Act would not be violated.

Comment: Commenters were divided about the provision of ancillary services through mobile units. Some believe that the use of mobile units and equipment leads to abusive arrangements. Other commenters supported the use of mobile units as cost-efficient means of sharing expensive DHS resources, particularly in rural areas. One commenter noted that State certificate of necessity (CON) volume requirements would be nearly impossible to meet without mobile units. The same commenter argued that sharing equipment is a critical part of cost containment, because idle equipment may lead to overutilization. One commenter pointed out that Federal antitrust agencies approve joint ownership of high technology equipment and that Blue Cross/Blue Shield has many policy provisions requiring joint ownership. These commenters generally advocated that mobile units be permitted and that mobile units qualify as a centralized location for the provision of DHS. A commenter observed that under the January 1998 proposed rule, a group practice could move any piece of equipment from office to office and, applying the "same building" requirements, use that piece of equipment for the provision of DHS. In light of this, the commenter questioned whether it made sense for the group practice to be prohibited from transporting the piece of equipment in a mobile vehicle to the various practice sites and using the equipment in the vehicle, if the mobile unit were exclusively used by the group practice and is not leased to any other health care provider. The commenter requested clarification that in these circumstances, the mobile unit would meet either the "same building" requirements or "centralized building" standard. Other commenters urged a broader exception

for mobile units, for example, including them if they are parked in the parking lot of a physician's medical office building or treating the units themselves as buildings.

Response: The treatment of mobile units presents difficult questions under section 1877 of the Act. On the one hand, we have serious concerns about the potential for fraud and abuse when services are provided with mobile units. These are the same concerns we have (and believe the Congress shares) about all shared physician-owned or controlled ancillary services facilities. We believe that section 1877 of the Act is aimed at arrangements that enable physicians to profit from referrals to free-standing, money-making services ventures that are not central to their medical practices. On the other hand, we agree that the statute clearly permits services provided by mobile units that qualify under the "same building" requirements. Thus, we agree with the commenter that a group practice can move any piece of equipment from office to office and use that "in-office" piece of equipment for the provision of DHS in a location that meets the "same building" requirements. Because we are defining "building" narrowly to exclude parking lots and interior parking garages, services provided in mobile vans or trailers will not comply with the "same building" requirements. We believe it reasonable to conclude that these services are not "in-office" when a van circulates among various physicians' offices and is rented serially by each. These arrangements would seem to be calculated to enhance physician revenues, rather than patient convenience, since patients would likely be encouraged, if not required, to schedule appointments on the day that the physician stands to profit from the services.

That said, we believe that mobile services can constitute an important part of the health care delivery system for many patients. Nothing in the statute or these regulations precludes a physician or group practice from arranging for a mobile provider to treat the physician's patients at his or her office location, so long as the financial arrangement, if any, between the physician or group practice and the ancillary services provider fits in an exception under section 1877 of the Act. In addition, in rural areas, the "rural provider" exception (to be addressed in Phase II of this rulemaking) may apply to protect some physician-owned mobile service providers. Finally, we are persuaded that the risk is low if a group practice exclusively owns and uses its own mobile van or trailer that

circulates among its group practice locations. In that limited circumstance, we are treating the mobile unit as akin to a "centralized" building under section 1877(b)(2)(A)(ii)(II) of the Act.

Comment: Several commenters sought clarification in the regulations text that group practices can have more than one centralized location for the provision of DHS. However, one commenter offered a contrary view. This commenter expressed the view that the Congress intended that the in-office ancillary services exception be interpreted narrowly with respect to centralized, free-standing locations. Specifically, the commenter cites the Conference Report for OBRA 1993 in H. Rep. No. 213, 1st Sess., 810 (1993), which states: "The conference agreement includes an exception for clinical laboratory services provided by a group practice with multiple office locations. For all other DHS the exception for group practices applies only if the services are provided in a centralized location" (emphasis added). Based on this language, the commenter believes that the Congress intended to permit group practices to have a single centralized location to provide DHS, but not to permit group practices to establish multiple wholly owned locations or franchises for DHS.

Response: Under section 1877(b)(2)(A)(ii)(II) of the Act, in the case of a referring physician who is a member of a group practice, services qualify for the in-office ancillary services exception if they are furnished "in another building which is used by the group practice * * * for the provision of some or all of the group's clinical laboratory services, or * * * for the centralized provision of the group's designated health services (other than clinical laboratory services)." Neither the statute nor the legislative history for this provision specifically requires one single centralized location for a group to provide DHS. In addition, we see no compelling reason to impose such a requirement. We are interpreting the word "centralized" to apply when a group practice has established a separate facility for furnishing DHS to patients, without the requirement that it service all of the practice's offices or provide all of the practice's DHS. We are incorporating this interpretation into the regulations text.

If we were to require only one centralized facility for DHS, a group practice could be in the position of having to send patients from some offices to inconvenient locations or to house a variety of different kinds of ancillary services in one location, such as combining all physical therapy, laboratory services, and x-rays in one

building. It may be entirely impractical for a group practice to house the equipment and staff for such diverse services in one location. We believe the Congress meant to allow groups to use this kind of "central" or dedicated location in situations in which the facility is convenient to some of the different offices, but as a result may not be physically attached to any one of them. Thus, the facility is "central" to multiple offices, rather than attached to just one.

Comment: Several commenters sought clarification that a group practice with a single office location for the delivery of services that are not DHS can have a separate, centralized building for the delivery of DHS.

Response: While we believe that the "centralized building" provision—which allows group practices to have "off-site" DHS locations—was intended to accommodate the concerns of group practices with multiple office locations that wanted to consolidate DHS operations for cost containment purposes, we can discern nothing in the statute or legislative history that would prevent a group practice with only one office location from using a centralized building for the provision of DHS.

However, we are concerned that allowing single and multi-office group practices to have multiple off-site locations for DHS would effectively gut the in-office ancillary services exception without additional controls. Accordingly, we are modifying the "centralized building" standard to ensure that DHS referrals protected by the in-office ancillary services exception are truly part of the group practice's medical practice. First, we are requiring that the centralized office space (whether an entire building, subpart of a building, or mobile unit) used for the provision of the group practice's clinical laboratory services or DHS qualifies for the exception only if it is used *exclusively* by the group practice or group practice physicians, that is, it is wholly owned by the group practice (other than a security interest held by an unrelated lender or mortgagor) or is leased or subleased by the group practice on a full-time basis (that is, 24 hours per day, 7 days per week, for at least 6 months). This rule precludes group practice shared facilities in off-site buildings. Second, part-time "centralized" DHS arrangements are precluded. For example, a group practice may not rent an MRI facility one day per week and treat that facility as a "centralized" building. Third, a mobile facility (for example, an x-ray van) owned and used exclusively by the

group practice will be considered a "centralized building."

Notwithstanding, group practices may lease or sublease DHS facility space (including mobile units) to or from other group practices or solo practitioners on a part-time basis. However, DHS provided to patients of part-time lessee or sublessee group practices will not fit in the in-office ancillary services exception, unless the "same building" requirements are met. Finally, referrals for ancillary services to a group practice from physicians not in the group practice or other group practices do not implicate section 1877 of the Act, provided there are no impermissible financial relationships between the parties. A referral for a designated health service does not create a financial relationship.

Comment: Many commenters urged us to establish a separate exception for shared facilities. Several commenters argued that shared facilities pose no greater risk of overutilization than DHS furnished by solo practices or group practices. Moreover, commenters believe that shared facilities overseen by referring physicians are likely to be more convenient, efficient, and accountable than other facilities. A number of commenters suggested that failure to protect shared facilities would disrupt existing arrangements that are widespread in the industry (as one commenter stated, shared facilities are the "reality of what's going on"), leaving many solo practitioners with only two options: merge with others to form group practices or disband their shared facilities. One physician commenter believes that if his shared radiology and clinical laboratory facilities are not permitted, the result would be a shift of income to commercial laboratory ventures, pathologists, and radiologists, further "dichotomizing" the incomes of primary care physicians and specialists. The physician claimed that his income would drop by 25 percent and that he would have to fire employees and default on a lease. Commenters representing the interests of solo practitioners asserted that there is no meaningful distinction between DHS facilities shared by solo practitioners and group practice-owned DHS facilities.

A physician-oriented trade association and other commenters urged us to add a new exception to allow the legitimate use of shared office facilities by physicians modeled on language included in BBA 1997, but never enacted. Other commenters offered different formulations, including allowing shared facilities if they are in the same building or complex of

buildings as the solo practitioners' office practices.

Response: In the August 1995 final rule and the preamble to the January 1998 proposed regulation, we observed that the in-office ancillary services exception would allow certain shared facility arrangements among solo practitioners who do not wish to become a group practice. For example, we noted that two solo practitioners who share an office and jointly own a laboratory can continue to refer to that laboratory, as long as each physician (1) furnishes physician services unrelated to the furnishing of DHS in the office (that is, the arrangement meets the "same building" requirements), (2) directly supervises the laboratory services for his or her own Medicare or Medicaid patients while they are being furnished, and (3) bills for the services. We further noted that if only one of the solo practitioners owns the laboratory in a shared office, the nonowning physician can refer to the laboratory as long as he or she is not receiving compensation from the owner in exchange for referrals. We solicited comments on the effects of section 1877 of the Act on other shared facility arrangements.

After careful review of the public comments, we are persuaded that our original approach in the January 1998 proposed regulations is most consistent with the purposes of section 1877 of the Act. Under that approach, shared facilities are permitted if they comply with the supervision, location, and billing requirements of the in-office ancillary services exception. With respect to the location of the shared facility, Phase I of this rulemaking permits shared facilities that meet the "same building" requirements. (However, shared facilities do not qualify under the "centralized building" standard because they will not meet the *exclusively used* requirement). Thus, as noted above, two solo practitioners who share an office and jointly own a laboratory can continue to refer to that laboratory, as long as each physician furnishes substantial physician services unrelated to the furnishing of DHS in the building where the laboratory is located, provides (directly or through an independent contractor if permitted under applicable payment and coverage rules) the appropriate level of supervision for DHS for his or her own Medicare or Medicaid patients, and bills for the services. We believe the relaxation of the direct supervision requirement under these regulations will enable additional shared facilities to come within the exception. Additionally, if only one of the solo

practitioners owns the laboratory in a shared facility arrangement, the nonowning physician can refer to the laboratory as long as he or she is not compensated by the owner in exchange for referrals.

We are not persuaded, however, that a separate exception for shared facilities is warranted. The BBA 1997 language that several commenters proffered would apply to services that are furnished—

- Personally by the referring physician who is a shared facility physician or personally by an individual directly employed or under the general supervision of such a physician;
- By a shared facility in a building in which the referring physician furnishes substantially all of the services of the physician that are unrelated to the furnishing of shared facility services;
- To a patient of a shared facility physician; and
- That are billed by the referring physician or a group practice of which the physician is a member.

Given that we are revising the supervision standards under the in-office ancillary services exception, we believe that the in-office ancillary services exception will cover most, if not all, of the nonabusive shared facility arrangements that would have been protected by this commenter's proposed additional exception.

Comment: A commenter questioned the application of the proposed regulations if physicians who share a building, but for legal or personal reasons are not formally organized into a professional structure (that is, a "single legal entity"), form a joint venture to establish a clinical laboratory or other ancillary service provider.

Response: As explained above, solo practitioners may own and operate shared DHS facilities so long as they fit in the in-office ancillary services exception. If the practitioners form a separate joint venture to provide the services, they may run into problems complying with the billing requirements of the in-office ancillary services exception, if the joint venture does the billing (that is, the joint venture will not qualify as a wholly owned entity and, therefore, will not fit into any of the in-office ancillary billing requirements under section 1877(b)(2)(B) of the Act or § 411.355(b)).

4. The Billing Requirement

The Existing Law: To qualify for the in-office ancillary services exception under the statute, the DHS must be billed by one of the following:

- The physician performing or supervising the service;
- The group practice of which such physician is a member, under that group practice's billing number; or
- An entity that is wholly owned by the referring or supervising physician or the referring or supervising physician's group practice.

The Proposed Rule: In the proposed regulation, we interpreted the billing requirements to allow a single group to bill under more than one billing number assigned to the group and to allow an agent to bill for the group in the group's name, using the group's number, provided the billing arrangement meets the requirements in § 424.80(b)(6). We further interpreted the "wholly owned" entity provision to mean that a physician or group practice can establish a wholly owned provider of DHS that can bill Medicare or Medicaid on its own behalf, under its own billing number that is not a group billing number.

The Final Rule: As with the other requirements in this exception, the billing requirements serve to tie the ancillary services for which self-referrals will be permitted to the physician's routine medical practice. Phase I of this rulemaking incorporates the OBRA 1993 amendment clarifying that in-office ancillary services that are billed by a group practice of which the referring or supervising physician is a member must be billed under a billing number assigned to the group practice. However, group practices may have, and bill under, multiple group practice billing numbers, subject to any applicable Medicare or Medicaid program restrictions. Wholly owned entities that qualify to do the billing under the rule may use their own billing numbers and need not use a number assigned to the physician or group practice that owns them. The entities must be *wholly* owned either by the physician performing or supervising the services or by the group practice; joint ventures between group practices and individual group practice physicians or that include other providers or investors do not qualify as wholly owned entities.

Billing may be done by independent third party billing companies if they are acting as agents of a solo practitioner, group practice, or entity, but the billing must be done under billing numbers assigned to the solo practitioner, group practice, or entity, and the services may not be separately billed under a billing company's number. The billing arrangements must meet the requirements of § 424.80(b)(6).

The express billing requirements of section 1877(b)(2)(B) of the Act contain

no billing method applicable to supervising independent contractor physicians who are "physician in the group" under section 1877(b)(2)(A)(i) of the Act and § 411.351, but who are not members of the group under § 411.351 (these physicians cannot bill themselves as the supervising physician because they are required to reassign their billing rights to the group in order to qualify as "physicians in the group"). We believe the Congress intended the billing requirements of section 1877(b)(2)(B) of the Act to correspond with the supervision requirements of section 1877(b)(2)(a)(i) of the Act and that this omission was simply a legislative drafting oversight.

Accordingly, we are interpreting the billing requirements to be consistent with the supervision requirements, which permit supervision by a "physician in the group." Therefore, the billing conditions will be satisfied if the DHS are billed by the group practice when the supervising physician is a "physician in the group."

In summary, under the regulations in Phase I of this rulemaking, to qualify for the in-office ancillary services exception, DHS must be billed by one of the following:

- The physician performing or supervising the service.
- The group practice of which such physician is a member, under that group practice's billing number.
- The group practice if the physician is a "physician in the group practice," under that group practice's billing number.
- An entity that is wholly owned by the referring or supervising physician or the referring or supervising physician's group practice.

Comment: One commenter objected to our interpretation of the "wholly owned" entity provision as unsupported by the statute. The commenter believes that allowing separate and distinct entities to provide services and bill on their own behalf would frustrate efforts to detect fraud and abuse, because the provider numbers of the physician making the referral and the entity providing the DHS would not be clearly linked on a claim form. The commenter believes that the Congress likely intended to exempt only wholly owned entities that primarily provide administrative and billing services.

Response: We find nothing in the statutory language that would limit wholly owned entities under section 1877(b)(2)(B) of the Act to entities that provide only administrative and billing services. Rather, we believe the wholly owned entity provision can be read reasonably to permit group practices to

provide DHS and bill through these entities. A narrower interpretation would seem to imply that the group practices could only bill using third party billing companies if these companies were wholly owned by the group. We believe it unlikely that the Congress intended such an interpretation.

Comment: A commenter suggested that the billing provisions in the in-office ancillary services exception be changed to include billing by a hospital for physician services furnished under arrangements. This change would allow physician services for hospital patients to come within the in-office ancillary services exception.

Response: The in-office ancillary services exception is designed to exempt from the referral prohibition certain DHS that are provided within a group practice. As discussed in section VIII of this preamble, DHS provided under arrangements with a hospital are inpatient or outpatient hospital services for purposes of the statute. We believe the Congress did not intend to protect inpatient and outpatient hospital services under the in-office ancillary services exception. In fact, in describing the in-office ancillary services exception in H. Rep. No. 111, 103d Congress, 1st Sess. 546 (1993), the Congress pointed out that services provided by a hospital or other provider "under arrangement" with a group practice are not protected under the general exception for in-office ancillary services. "Under arrangements" issues are further discussed in section VIII.M of this preamble.

C. Group Practice Definition (Section 1877(h)(4) of the Act)

The Existing Law: As defined in section 1877(h)(4) of the Act, a "group practice" is a group of two or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association, that meets certain conditions. Section 1877(h)(4) of the Act was promulgated as part of the original section 1877 law and later amended by OBRA 1993. The current law contains the following conditions applicable to "group practices" for purposes of section 1877 (those conditions added by OBRA 1993 are so noted):

- Each physician member of the group furnishes substantially the full range of services that the physician routinely furnishes, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities,

equipment, and personnel (the "full range of services" test).

- Substantially all of the services of the physician members of the group are furnished through the group, are billed under a billing number assigned to the group, and amounts so received are treated as receipts of the group (the "substantially all test") (revised by OBRA 1993).

- The overhead expenses of and the income from the practice are distributed in accordance with methods previously determined (modified by OBRA 1993).

- No physician member of the group directly or indirectly receives compensation based on the volume or value of referrals by the physician, with the exception of certain profits and productivity bonuses (added by OBRA 1993).

- Members of the group personally conduct at least 75 percent of the physician-patient encounters of the group practice (the "75 percent physician-patient encounters test") (added by OBRA 1993).

- The group practice complies with all other standards established by the Secretary in regulations.

In addition, section 1877(h)(4)(B) of the Act establishes two "Special Rules"—

- A physician in a group practice may be paid a share of the overall profits of the group, or a productivity bonus based on services personally performed or services incident to the personally performed services, so long as the share or bonus is not determined in any manner that is directly related to the volume or value of referrals by the physician (added by OBRA 1993); and

- In the case of a faculty practice plan associated with a hospital, institution of higher education, or medical school with an approved medical residency training program in which physician members may furnish a variety of different specialty services and furnish professional services both within and outside the group, as well as perform other tasks such as research, the conditions contained in the definition of "group practice" apply only with respect to the services furnished within the faculty practice plan.

Our August 1995 final rule covering clinical laboratory services referrals defined "group practice" at § 411.351 based on the statute as it read effective January 1, 1992. At that time, we interpreted the "substantially all test" to mean that at least 75 percent of the patient care services (defined as services addressing the medical needs of specific patients) of the group practice members must be furnished through the group. We interpreted members of the group to

include owners, employees, and independent contractors. We required that the group practice be “a single legal entity.” Finally, we stated that the “substantially all test” would not apply to any group practice that is located solely in a health professional shortage area (HPSA). For group practices located outside of a HPSA, the rule provided that any time spent by group practice members providing services in a HPSA would not be used to calculate whether the group practice located outside the HPSA had met the “substantially all test.”

The Proposed Rule: We proposed several changes to the definition of “group practice” in § 411.351 to incorporate OBRA 1993 changes. We also proposed several other significant changes. First, we proposed a “unified business test”—targeted at sham group practices—that would require group practices to exhibit “centralized decision making, a pooling of expenses and revenues, and a distribution system that is not based on each satellite office operating as if it were a separate enterprise.” Second, we proposed excluding independent contractors as members of the group to ease compliance with the “substantially all test.” Third, we proposed expanding our definition of “patient care services” to include any of a physician’s tasks that address the medical needs of specific patients or patients in general or that benefit the group practice.

Final Rule: As with the in-office ancillary services exception, we have been guided in developing the final definition of “group practice” by twin goals: (1) To minimize the regulatory intrusiveness of the definition while giving meaning to the statutory language and intent; and (2) to provide clear guidance as to what constitutes a “group practice” for purposes of section 1877 of the Act. We understand the importance of group practice status to physicians: simply stated, it allows group members to refer patients to one another (or to the group itself) for DHS payable by Medicare or Medicaid, and it allows group members to share in profits derived from such DHS. Section 1877 of the Act recognizes that referrals within groups are commonplace and may be appropriate adjuncts to a group’s core medical practice.

As an initial matter, the definition of “group practice” promulgated in the statute and these regulations applies only for purposes of section 1877 of the Act and may have little or no bearing for purposes of other Medicare or Medicaid provisions. For example, the definition of a “physician group” under the physician incentive plan rules is

broader than the definition of “group practice” under section 1877 of the Act.

A common complaint about our January 1998 proposed regulation was that it would exclude many *bona fide* group practices, intrude too far into the business and financial operations of physician practices, and chill group practice integration that is crucial in an increasingly managed care environment. We have been mindful of these concerns in developing Phase I of this rulemaking. It is not our intent to micro-manage group practices or dictate their organization or operation; rather, our intent is to define “group practice” so as to create, consistent with our understanding of the statutory intent, a meaningful exception to the general referral prohibition under section 1877 of the Act, an exception that permits certain traditional and commonplace referral patterns within group practices, without permitting the exception to swallow the rule. In general, Phase I of this rulemaking is more expansive than our January 1998 proposed rule and affords physicians substantial flexibility in designing and managing their medical practices (subject, of course, to any other legal impediments imposed by Federal or State law).

We believe the group practice definition set forth in section 1877(h)(4) of the Act is premised on two assumptions. First, internal group practice referrals should only be protected under the physician services or in-office ancillary services exceptions (both of which apply in specific ways to group practices) if the group practice is a *bona fide* group practice and not a loose confederation of individual physicians bound together primarily to profit from DHS referrals. We believe the Congress intended a true group practice to consist of physicians whose practices are fully integrated, medically and economically. In short, the physicians practice medicine together in a single group, not separately, and their financial prospects are interdependent. Thus, the Congress imposed certain tests that demonstrate the requisite integration and gave the Secretary regulatory authority to impose additional tests. If true integration is present, we do not believe the Congress otherwise intended to regulate the formal structure and operation of the group. Second, the financial incentives for group practice physicians to generate referrals of Medicare or Medicaid payable DHS for the group should be attenuated. Thus, the group practice definition provides that group practice physicians may not be paid directly or indirectly based on the volume or value of DHS referrals, unless the

compensation is a profit share or productivity bonus that is only indirectly related to those referrals.

With these precepts in mind, Phase I of this rulemaking incorporates the following significant revisions:

- Broadening of the types of arrangements that qualify as a “single legal entity” to include, among other things, multi-entity legal structures and structures owned by a single physician.
- Adoption of our proposal to exclude independent contractors from the definition of a “member of the group.” However, independent contractors who meet the conditions set forth at § 411.351 may qualify as “physicians in the group practice” who may receive profit shares and productivity bonuses under section 1877(h)(4)(B)(i) of the Act.
- Adoption of our proposed expanded definition of “patient care services” so that patient care services include all services a physician performs that address the medical needs of specific patients or patients in general or benefit the group practice (for example, administrative services for the group).
- Expansion of our 1998 proposal to gauge compliance with the “substantially all test” by measuring a physician’s actual time spent on patient care services by permitting groups to adopt other reasonable methods for determining compliance.
- Creation of a substantially more flexible definition of a “unified business” that will permit group practices to use cost- and location-based accounting with respect to services that are not DHS, and, in some cases, with respect to services that are DHS if the compensation method is not directly related to the volume or value of the physician’s referrals and other conditions are satisfied.
- Revision of the productivity bonus rules so that group practices may pay member physicians and independent contractors who qualify as “physicians in the group” productivity bonuses based directly on the physician’s personal productivity (including services incident to such personally performed services that meet the requirements of section 1861(s)(2)(A) of the Act and section 2050 of the Medicare Carriers Manual, Part 3), but may not pay such physicians any bonus based directly on their referrals of DHS that are performed by someone else.
- Promulgation of specific methods for ensuring that compensation for DHS is only indirectly related to referral income. In addition, parties may use other methods that are reasonable and documented.

- Elimination of the group practice attestation requirement.

These revisions and others are discussed in the comments and responses that follow. Each comment and response section begins with an overview of the relevant provision in the group practice definition and a summary of the final rule relating to that provision. The sections are divided as follows: General comments, the single legal entity requirement, members of the group, the "full range of services" test, the "substantially all" test, and the "75% physician-patient encounters" test.

1. General Comments

Comment: Many commenters, including a group practice trade association, criticized the proposed regulations for group practices as overly intrusive into the internal operations of physician practices, unnecessarily complex, and incapable of implementation in a fair and reasonable manner. The association and other commenters believe that the Congress intended the group practice provisions in the law predominately to regulate the external ownership, compensation, and referral arrangements of physicians and not the inner workings of group practices themselves. The association and other commenters protested that the rules create arbitrary distinctions among different types of physicians. These commenters contended that no tenable reason exists to treat group practices, pathologists, radiologists, and radiation oncologists—all of whom are permitted under the statute or various exceptions to make referrals to entities with which they have financial relationships under certain circumstances—differently than other physicians, since they have an equal incentive to self-refer.

Response: As indicated above, in preparing Phase I of this rulemaking, we have been mindful of the commenters' concerns about the intrusiveness of the proposed rule, and have sought to minimize the regulatory impact of the group practice definition and to provide clear guidance as to what constitutes a "group practice" for purposes of section 1877 of the Act. We do not intend to use these regulations to micro-manage group practices or to dictate their organization or operation, except as is necessary to give effect to the statutory intent of the Congress to create a limited exception to the general referral prohibition for DHS referrals by physicians within their own group practices. In general, Phase I of this rulemaking is broader than the January 1998 proposed rule and affords physicians substantial flexibility in

designing and managing their medical practices.

While we have endeavored to apply these rules as equally as possible to solo and group practitioners and among various types of practitioners, some differences in regulation and outcomes are unavoidable, and in some cases desired, given the wide array of arrangements to which the statute applies and the distinctions inherent in the statutory scheme. For example, the Congress included a specific exception for referrals by consulting pathologists, diagnostic radiologists, and radiation oncologists that does not apply in the case of other consulting physicians. The Congress intended disparate treatment of these consulting physicians, reasonably, we believe, because of the limited ability of pathologists, diagnostic radiologists, and radiation oncologists to generate patient referrals of services they either perform or supervise. Similarly, the Congress judged referrals within group practices (and solo practices) deserving of special consideration based, we believe, on a recognition of physicians' traditional practice of delivering DHS in their own offices to their own patients.

Comment: A commenter sought clarification as to whether a group practice was exempt from section 1877 of the Act. Several commenters observed that group practice status does not, by itself, protect against the risk of overutilization of ancillary services provided by the group.

Response: A group practice is not exempt from section 1877 of the Act by virtue of being a "group practice" under the definition in section 1877(h)(4) of the Act and § 411.352 of these regulations. A relevant exception, such as the in-office ancillary services or the physician services exceptions, must still apply.

Comment: Several commenters suggested that section 1877 of the Act and the regulations should focus on referrals of medically unnecessary tests to entities with which physicians have prohibited financial relationships. Some commenters suggested that we use our utilization data to develop norms for each physician specialty that could be the basis for measuring appropriate utilization and preventing inappropriate referrals.

Response: We disagree that section 1877 of the Act should apply only to referrals of unnecessary items and services. While overutilization is a principal concern of the statute, and a primary focus of this rule, nothing in the statute suggests that the Congress intended to limit the statute's reach to referrals of medically unnecessary tests

or procedures. Rather, the statute applies to all referrals of DHS to entities with which a referring physician has a prohibited financial relationship. The statute is designed to create a bright line that prohibits a high risk category of financial relationships and relieves the government from having to "look behind" every physician referral.

2. Single Legal Entity Requirement

The Existing Law: Under the statute, a group practice must consist of "two or more physicians who are legally organized as a partnership, professional corporation (PC), foundation, not-for-profit corporation, faculty practice plan, or similar association." The August 1995 final rule took the position that a group practice could consist of only one legal entity and that any individual or entity could organize, operate, or control a group practice, as long as two or more physicians had a role in providing services and the group met all of the other specific requirements for being a group practice under section 1877 of the Act. Thus, for example, a hospital could "own or operate" a group practice, provided no State law prohibited it.

The Proposed Rule: The January 1998 proposed regulations retained the interpretation of the single legal entity requirement from the August 1995 rule, requiring the legally organized group practice to consist of a "single legal entity", that is, one legal entity identified as the group practice that meets all of the group practice definitional tests. In addition, the January 1998 proposed regulations proposed allowing individual physicians who are incorporated as individual professional corporations to form a group practice, subject to meeting the remaining conditions of the group practice definition.

The Final Rule: We are retaining and incorporating into the regulations text the "bright line" rule that a group practice must be a single legal entity. The single legal entity can assume any form recognized by the State in which the entity achieves its legal status, including, but not limited to, a corporation (for-profit, professional, or nonprofit), partnership, foundation, faculty practice plan, or limited liability company. The single legal entity can be legally organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities. The single legal entity must be formed primarily for the purpose of being a physician group practice. Hence, for example, a hospital that employs physicians is not a "group practice" for purposes of

section 1877 of the Act, although the hospital can form or acquire a group practice that is a separate single legal entity. The following structures are among those that may qualify under Phase I of this rulemaking, assuming all other requirements of the group practice definition are satisfied:

- A partnership between two or more physicians.
 - A partnership between one physician and another party, provided that the partnership employs at least one other physician. (Similarly, a partnership between two nonphysician parties can qualify if it employs at least two physicians).
 - A corporation or limited liability company with one or more physician shareholders or members, provided that a corporation or limited liability company with only one physician shareholder or member employs at least one other physician.
 - A corporation or limited liability company owned by nonphysicians, provided it employs at least two physicians.
 - A single legal entity owned by two or more physicians through their individual professional corporations.
 - A solo practitioner who is organized as a legal entity (for example, a professional corporation) and employs at least one other full-time physician.
 - A single legal entity (whether a corporation, limited liability company, or other form) owned by one or more other legal entities (that is, a multi-entity arrangement) that involves two or more physicians through employment or indirect ownership, provided that the “investing” or “owner” entities are not themselves functioning group practices. (In other words, existing groups may not band together to form a group practice primarily to share in-office ancillary referrals.) It is our understanding that the prevalent practice in these kinds of arrangements is for the physicians who own the investing entities to become employees of the new group practice, and for the investing entities themselves to cease functioning as group practices.
- This list is illustrative only, and other variations are possible. What is essential is that there must be one identifiable legal entity that is a *bona fide* group practice of two or more physicians. The definition of group practice does not include a loose confederation of physicians, a substantial purpose of which is to share profits from referrals (sometimes referred to as a “group practice without walls”), or separate group practices under common ownership or control through a physician practice management

company, hospital, or health care system, or other entity or organization.

We have responded to public comments regarding problems faced by faculty practice plans under section 1877 of the Act by using our regulatory authority under section 1877(b)(4) of the Act to create a new exception applicable to faculty practice plans. This new exception is discussed in section VII.A of this preamble.

While several commenters requested accommodation in the group practice definition for bifurcated foundation-model group practices (that is, arrangements between a nonprofit entity that provides health care services and a physician group, typically used in States that restrict the corporate practice of medicine), we have determined that those arrangements are better addressed by the personal service arrangements exception. As noted elsewhere in this preamble, we intend to apply our uniform interpretation of the volume or value standard to all exceptions in which it appears. (See the discussion in section V of this preamble.)

Comment: Many commenters concurred with our position that a group practice can be organized by any individual or entity, but took issue with other aspects of our group practice organizational tests. As a threshold matter, a number of commenters maintained that the statute does not require a “single legal entity.” These commenters generally fell into three categories: (1) Commenters seeking protection for foundation model “groups” in States that follow the corporate practice of medicine doctrine, (2) commenters seeking protection for physician “groups” practicing in academic medical settings, and (3) commenters seeking protection for “groups” that are under common ownership or control, but that are not bound together in a single legal entity. Comments on the first two issues—foundation models and academic medical settings—are summarized and addressed elsewhere in this section and in section VII.A of this preamble.

As to the third category—common ownership and control—commenters generally requested that we recognize organizations under common control as a single unit or group practice, as we do in our definition of “hospital” in § 411.351 (Definitions) of the regulations. (Section 411.351 reads as follows: “Hospital * * * refers to any separate legally-organized operating entity plus any subsidiary, related entity, or other entities that perform services for the hospital’s patients and for which the hospital bills.”) Specifically, the commenters suggested

we interpret this portion of the group practice definition as covering a single legal entity that includes any separate, legally-organized operating entity plus any subsidiary, related entity, or other entities that perform services for the group practice’s patients and for which the group practice bills. Some commenters noted that the ability to have subsidiaries is important for groups for valid, nonabusive business reasons, such as to operate in more than one State when States have different corporate requirements, to organize components of the continuum of care such as home health or skilled nursing care, and to operate as multi-entity integrated delivery systems. Some commenters indicated that some State laws require physicians to practice in a different entity when working in a bordering State. Also noted was that complex corporate structures are sometimes required for a variety of other legitimate business reasons, such as allowing groups to meet State licensing requirements, to allocate the risk of liability, to comply with inconsistent State regulations, or to meet corporate practice of medicine requirements. Similarly, these commenters maintained that an aggregation of groups managed by the same physician practice management company or multiple groups owned by the same hospital should be considered a “group practice” for purposes of section 1877 of the Act.

Response: Having considered the comments, we iterate our view that a group practice must be a “single legal entity.” A standard that would allow entities under common ownership or control to be a group practice under section 1877(h)(4) of the Act does not sufficiently protect against sham group practice arrangements or loose confederations of physicians operating as a group practice substantially for purposes of profiting from DHS referrals. We find nothing in the statute that suggests that the Congress intended for a “group practice” to be so broadly construed as to include multiple group practices that happen to use the services of the same management company or that happen to be affiliated with the same health system. Single legal entities owned by multiple entities are permitted, as discussed in the response to the next comment. We address the special needs of foundation-based practices and faculty practice plans in this section and in section VII.A of this preamble, respectively.

Comment: Many commenters considered our proposed parameters for the composition of the “single legal entity” too restrictive, taking issue, in particular, with our statement that “the

statute specifically requires that a partnership consist of two or more physicians who are partners and that a PC consist of two or more physicians who are incorporated together." While several commenters commended our proposal to allow group practices to include individual professional corporations that employ their own shareholders, commenters generally espoused expanding the group practice definition to include any physician group (regardless of its ownership) that is organized as a distinct legal entity and that employs more than one physician, provided that all of the other group practice definitional tests are met.

In these commenters' view, prohibiting a sole practitioner from owning a group practice that employs multiple physicians is unfair, inconsistent, anticompetitive, and not supported by the statutory language. The commenters pointed out that, under our January 1998 proposed rule, a hospital could own a group practice, but an individual physician could not. Commenters believe that the other requirements for meeting the group practice definition prevent any sham practice arrangements and that an interpretation requiring direct ownership by two physicians does not further Federal fraud and abuse policy.

A number of commenters asked that we clarify that a group practice may be owned by any legal corporate structure or arrangement including, but not limited to, limited liability companies, multi-member professional corporations, sole physician shareholder companies that employ at least one physician, hospitals that employ physicians, entities owned jointly by physicians and a hospital (for example, a physician hospital organization (PHO)), or general corporations that employ two physicians without any physician ownership. This interpretation is consistent with the August 1995 final rule. In particular, several commenters observed that group practices commonly are formed through the merger of existing group practices. The merging practices typically contribute assets and transfer physicians and other employees to the new group practice entity, which bills for the physician services under a group billing number and treats amounts received as receipts of the new group practice, and which meets the other group practice definitional requirements. The commenter urged that the new group practice entity should qualify for group practice status, without having to dissolve the merging shareholder entities, which are often maintained for

tax or other purposes unrelated to Medicare or the fraud and abuse laws.

To prevent sham group practices, one commenter suggested that, in the case of a new group practice formed by the merger of existing group practices or professional corporations, we should require the new group practice to employ its members rather than allowing the multiple professional corporations (PCs) that formed the new group to continue employing practice members (except in the case of an individual professional corporation that employs a physician and owns a stake in a group practice). Similarly, another commenter recommended requiring all group practices (regardless of layers of composition) to be fully integrated into a single operating medical business at the top or "group" level. A group practice would be deemed fully integrated if it met the group practice definitional tests and presented itself as a single medical business whose equity holders operate as a single business by sharing such things as contracts, liability, facilities, equipment, support personnel, management, and a pension plan. A fully-integrated group would be required to employ or contract with all physicians at the group level so that physician compensation and accounts receivable of all members of the group would be "at risk" in the event of losses due to poor management of the group or in the event of a malpractice claim against any member of the group.

Response: We generally agree with the commenters. We have reconsidered the statutory language and believe that the provision requiring "a group of 2 or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association—" can be interpreted in several ways. It can reasonably be read to mean that a group must consist of some kind of legally organized entity, owned by virtually any combination of individuals or other entities, provided that there are at least two physicians providing services to patients as group practitioners. We have amended the definition of a group practice accordingly in § 411.351. We believe this interpretation allows us to treat all practices, regardless of who owns or operates them, more uniformly. The introduction to this section provides an illustrative list of possible group practice organizational structures.

We are adopting the commenters' suggestion that no entity that owns all or part of a group practice (that is, no equity holder in the group) may itself function or qualify as a group practice (whether a group practice under section

1877(h)(4) of the Act or otherwise). Thus, for example, in the case of a new group practice formed through the merger of existing group practices, the merging or defunct group practices may not themselves operate as medical group practices (that is, they may not furnish or bill for health care services); however, the defunct practices are not required to dissolve. The merging group practices should transfer all medical assets to the new group practice, and the new group practice should employ the physicians and bill for their services, treating receipts as receipts of the new group practice.

We also generally agree that a group practice should consist of a single medical business whose equity holders operate as a single business by sharing such things as contracts, liability, facilities, equipment, support personnel, management, and a pension plan. This aspect of a group practice is addressed by the unified business test in § 411.352 of the regulations. (See section VI.C.7 of this preamble for additional information).

Comment: Commenters questioned whether a hospital could qualify as the "single legal entity" needed to establish group practice status. In the August 1995 regulations, we stated that " * * * if a clinic (or other facility) is legally organized to include two or more physicians and provides the services of physicians, it is a group practice, even if it is established, operated, and controlled by a nonphysician group or corporation. This would be so regardless of who employs the physicians (in the scenario presented by the commenter, the clinic physicians were employed by the hospital that established the clinic)." (60 FR 41937) One commenter interpreted this language to mean that a hospital, which is itself a legal entity, could employ physicians and, therefore, qualify as a group practice if the other requirements of the group practice definition were met. Thus, the hospital would not need to establish a separate legal entity for its employed physicians to be considered a group practice. A related concern was whether a single hospital could encompass multiple group practices. According to the commenter, the ability of hospitals to establish multiple groups is especially important for a hospital entity that may operate several campuses in different cities as unincorporated divisions, a situation likely to increase as providers consolidate into regional networks.

Response: We believe the commenter's interpretation would stretch the meaning of a "group practice" too far. We do not believe that a hospital can reasonably be construed

as a "group practice." We find no basis to conclude that the Congress thought otherwise. The statement from the August 1995 regulations was made in response to a comment regarding an arrangement in which a tax-exempt hospital had affiliated group practices and established a separate tax-exempt physician-directed clinic as the group practice's operating entity, but employed the physicians in the affiliated groups directly. In responding to the comment, we attempted to make two points: (1) That a group practice need not be legally organized by physicians; and (2) that a physician-directed clinic could qualify as a group practice.

We iterate that a group practice may be legally organized by a hospital or other nonphysician person or entity; however, neither the hospital itself nor any other facility the primary purpose of which is something other than to operate a physician group medical practice, can be a group practice. A hospital may establish multiple group practices through subsidiaries or affiliated entities that are separate legal entities. Each entity may be a group practice for purposes of section 1877 of the Act, although the aggregation of groups will not be. Exceptions, such as the in-office ancillary services exception, would only apply to referrals within one of those groups and not across multiple groups within the same hospital entity.

Comment: A commenter noted that the August 1998 proposed rule clearly states that a hospital may own and operate a group practice (assuming there is no State law impediment to such ownership) and that physicians may own a group indirectly through individual professional corporations. In light of these statements, the commenter sought clarification on three points: (1) Whether a single legal entity owned jointly by physicians and the parent company of a hospital could qualify as a group practice, provided all of the other conditions in the definition were satisfied; (2) whether the "single legal entity" test could be met by a limited liability company; and (3) whether several physicians organized as a limited liability company could, in turn, own another entity (for example, a second limited liability company) that could qualify as a group practice.

Response: In responding to the commenter's questions, we apply the principles described above. First, a single legal entity owned jointly by physicians and the parent company of a hospital could qualify as a group practice, provided all of the other conditions in the definition were

satisfied. Second, a limited liability company duly organized under applicable State law could qualify as a "single legal entity." Third, several physicians organized as a limited liability company could, in turn, own another entity that could qualify as a group practice provided that the first limited liability company is not, and does not operate as, a group practice. In this last case, the physician members of the first limited liability company would be considered members of the group by virtue of their indirect ownership interest in the second entity.

Comment: Commenters note that health systems, management companies, hospitals, and other nonprofit and for-profit corporations must comply with State laws governing the corporate practice of medicine. In some States, these laws restrict or prohibit a corporation from directly employing physicians. In some cases, the corporations form a "captive" or "friendly" professional corporation with one physician owner who holds the ownership rights to the professional corporation in trust for the corporation. The friendly professional corporation directly employs physicians who then form the group practice. The corporation manages the business of the group practice, with the sole physician shareholder acting primarily as a "figurehead." The arrangement ensures that the corporation only indirectly employs the physicians and does not violate the corporate practice of medicine rules. Commenters noted that typically only one physician is a shareholder in the friendly professional corporation so that day-to-day transactions are less cumbersome.

Response: Since we have amended the group practice definition to cover groups that consist of one physician owner and one or more physician employees, we believe that the types of "captive" or "friendly" professional corporations described in the comment can both meet our definition and comply with corporate practice of medicine requirements. Groups must continue to meet all of the other criteria in the group practice definition in section 1877(h)(4) of the Act and § 411.351.

Comment: Several commenters asked that we clarify whether the "single legal entity" requirement precludes a group practice from having subsidiary entities that, for example, own real estate or equipment, provide billing services, or operate ancillary services.

Response: As we noted in the August 1995 final regulations, we believe that the statute does not preclude a single group practice from owning other legal

entities for the purposes of providing services to the group practice. Thus, to cite the example in the August 1995 final regulation at 60 FR 41936, a group practice could wholly own and separately incorporate a laboratory facility that provides laboratory services to a group practice or other patients. The physicians could qualify for the in-office ancillary services exception provided they meet the requirements for supervision, location, and billing. The billing requirement in section 1877(b)(2)(B) of the Act allows services to be billed by the referring or supervising physician, the group practice, or an entity wholly owned by the group practice. The exception appears to anticipate that a group practice may wholly own separate legal entities for billing or for providing ancillary services. Parties should be aware, however, that the group practice safe harbor under the anti-kickback statute (§ 1001.952(p) of this title), does not protect group practice ownership of ancillary services; for purposes of the anti-kickback statute, these arrangements are evaluated on a case-by-case basis.

3. Members of the Group

The Existing Law: Under the August 1995 final regulations, owners, employees, and independent contractors were all considered "members of a group" practice for purposes of the group practice definitional tests.

The Proposed Rule: The proposed regulations proposed modifying the definition of the term "members of the group" to include only physician partners, shareholders, and full-time and part-time physician employees. Independent contractors would no longer be considered members of the group. This change was proposed to aid group practices attempting to comply with the 75 percent "substantially all test." Physicians would be considered members of the group during the time that they furnish patient care services to the group.

The Final Rule: We are adopting our January 1998 proposal to define a member of a group practice as any physician who owns, or is employed by, the group practice. In the case of a group practice owned by professional corporations or defunct group practices, the physicians who own those entities will be considered members of the group practice. Also, those physicians who own all or part of the group practice through their own professional corporations and who are employed by their own professional corporations (which contract with the group practice to provide physician services) will be

considered members of the group. Physicians are members of the group during the time they furnish "patient care services" (as defined at § 411.351) to patients of the group or for the benefit of the group, even if those services cannot be billed by the group (for example, certain administrative services, *pro bono* services).

Independent contractors and leased employees will not be considered members of the group. The exclusion of independent contractors is intended to aid many group practices in complying with the "substantially all test" described below. Although not group practice members, under certain circumstances, independent contractors may provide the required supervision for the in-office ancillary services exception, as described in section VI.B.2 of this preamble.

While nonphysicians, such as nurse practitioners and physicians assistants, may be group practice "members" for general purposes under section 1877 of the Act, their membership will have no practical effect, since they are not "physicians" for purposes of the three group practice "tests" (the "full range of services," "substantially all," and "75 percent physician-patient encounters" test), nor for purposes of the profits and productivity bonuses provisions. While referrals by nurse practitioners and physician assistants generally do not trigger section 1877 of the Act, which applies only to physicians (as defined at section 1861(r) of the Act), referrals made by nonphysician health care professionals may implicate the statute if those referrals are directed or controlled by a physician. In other words, a physician or group practice cannot channel referrals through a nurse practitioner, physician assistant, or other nonphysician health care professional in order to circumvent the prohibition under section 1877, and any channeled referrals would be imputed to the responsible physician.

Comment: Many commenters supported our proposal to count owners and employees as members of the group, but not independent contractors. This change would facilitate compliance with the group practice definition by group practices that use part-time independent contractor physicians to supplement and expand the range of services the group offers to patients. Some commenters recommended that independent contractors be excluded only for purposes of the "substantially all test," but not for other purposes, including the direct supervision requirement of the in-office ancillary services exception and the 75 percent physician-patient encounters test. Some

commenters objected to excluding independent contractors from the definition of "members of the group" because they perceived that such exclusion would prevent group practices from paying independent contractors productivity bonuses for the work they personally perform under section 1877(h)(4)(B)(i) of the Act.

Response: We are retaining our proposal to exclude independent contractors from the definition of "members of the group practice." On balance, we believe this change will benefit many group practices that wish to qualify for group practice status. As to the other concerns raised by commenters, we believe those concerns have largely been addressed by other changes in these regulations. We have liberalized the direct supervision standard in the in-office ancillary services exception to permit supervision by independent contractors who meet certain conditions that establish that the independent contractors are "physicians in the group practice." (See discussion in section VI.B.2 of this preamble). As discussed below, in greater detail, we are permitting group practices to pay productivity bonuses to independent contractors who are "physicians in the group practice." (See discussion in section VI.C.8 of this preamble).

Comment: A number of commenters advocated a flexible approach to the definition of "member of the group," urging that groups be permitted to elect whether to include independent contractors as members on an annual or other basis. These elections would apply uniformly for purposes of qualifying under all of the group practice definitional tests and the in-office ancillary services exception, and would be reported to us.

Response: The election process described by the commenters strikes us as unnecessary given the significant changes in this final rule with respect to the treatment of independent contractors under the in-office ancillary services exception and the group practice productivity bonus provisions. In our view, an election process would impose an additional administrative burden on groups and the government, with minimal offsetting benefit.

Comment: To accommodate multi-entity group arrangements, a commenter suggested that "members of a group" should include owners of the group, employees of the group, and owners of any sole or multiple shareholder professional corporation that has an ownership interest in the group (that is, indirect owners).

Response: For purposes of the definition of "members of the group,"

we are including any physician owners of a sole or multiple shareholder PC or other entity that has an ownership interest in the group. In essence, we intend to "look through" any corporate or entity owners to the ultimate physician owners. Thus, members of the group include physicians who are owners (directly or indirectly) and *bona fide* employees of the group.

Comment: Several commenters suggested that independent contractors be permitted to qualify as group practice members on a *locum tenens* basis. Thus, for example, a group would be allowed to use independent contractors to provide coverage when a member of the group is ill and unable to practice medicine temporarily. Other reasons to use *locum tenens* physicians could include death or disability of a physician, resignation of a physician, accommodating seasonal increases in patient loads, and "trial runs" of physicians being recruited to join a practice. According to commenters, *locum tenens* providers are typically paid on a fee-for-time basis by the staffing organizations with which they are affiliated. Thus, they typically have no direct financial relationships with any of the health care entities to which they are assigned. The health care entities retain all patient receipts and, when possible, Medicare payments are reassigned to the health care entity.

Response: Nothing in section 1877 of the Act or these regulations prevents the use of *locum tenens* physicians in situations like those described in the comments. The issue raised, however, is how these physicians should be treated for purposes of a group practice's compliance with the group practice definition and how referrals by such physicians should be treated under the general prohibition under section 1877. As to the first issue, we believe an appropriate use of *locum tenens* physicians in exigent situations should not prevent a group practice that otherwise complies with the definition at section 1877(h)(4) and § 411.352 of these regulations from qualifying for group practice status. We are applying the rules at section 3060 "Reassignment," of the Medicare Carrier's Manual (HCFA Pub. 14-3), Part 3—Claims Process (the reassignment provisions) as the test for whether a physician is a *locum tenens* physician. A *locum tenens* physician will be considered as "standing in the shoes" of the regular physician (as defined in section 3060.7) if he or she replaces the regular physician in accordance with section 3060.7. We note that section 3060.7 does not treat a physician hired

on a “trial run” basis as a *locum tenens* physician.

Comment: One commenter sought clarification that on-call physicians who are independent contractors would be exempted from the group member and group practice requirements but would be able to provide and supervise care on behalf of a group member. On-call physicians for one group may be members of other group practices. They may or may not be compensated for their services or bill under the group practice billing number of the group for which they are serving in an on-call capacity. According to the commenter, on-call arrangements are commonplace, especially among groups that do not have sufficient numbers of specialists to cover for each other. The commenter requested a specific exemption under the statute so that on-call physicians do not impede groups from meeting the group practice definition and are not precluded from ordering DHS when they are serving in an on-call capacity. The commenter suggested an on-call physician be treated as “standing in the shoes” of the member while providing on-call services for purposes of the “substantially all test,” the 75 percent physician-patient encounters test, and the supervision requirement of the in-office ancillary services exception.

Response: We agree that it is appropriate to treat on-call physicians as “standing in the shoes” of the member while providing on-call services for purposes of the “substantially all test,” the 75 percent physician-patient encounters test, and the supervision requirement of the in-office ancillary services exception, provided that the services are billed by the practice for which the physician is serving on an on-call basis.

Comment: Several commenters questioned whether nurse practitioners, physician assistants, or other nonphysician providers could be group members, and if so, whether their services would count in the calculation of the 75 percent physician-patient encounters test.

Response: We perceive nothing in the statute that would prevent group practices from admitting nurse practitioners, physician assistants, or others as members of the group for purposes other than section 1877 of the Act. However, the definition of a “group practice” in section 1877(h)(4) of the Act contains several requirements that apply specifically to *physician* members of the group. Provisions of the in-office ancillary services exception and the physician services exception also refer specifically to physician members or physicians in the same group practice.

The term “physician” is specifically defined under the Medicare statute at section 1861(r) of the Act and does not include nurse practitioners or physician assistants. Any services that these individuals provide are not counted under the “substantially all test” or under any other part of the group practice requirements or exceptions that apply to physician members.

The referral prohibition in section 1877 of the Act applies only to referrals that are made by a physician to an entity with which that physician, or an immediate family member, has a financial relationship. If a nonphysician practitioner is referring a physician’s patients at the physician’s suggestion or in lieu of the treating physician, we would impute the referrals to the physician. Simply stated, physicians may not delegate their own referrals to avoid the referral prohibition. On the other hand, we would not impute the referrals if the nurse practitioner or the physician assistant is independently treating the patients and initiates the referrals on his or her own. We think the determination will depend on the specific facts and circumstances.

Comment: One commenter asked that we exclude from the definition of members of the group any employees who provide interpretation or supervision services only and are not otherwise involved in patient care.

Response: Given the revisions we have made in Phase I of this rulemaking to the in-office ancillary services exception and the group practice definition, we see no need for a special exclusion for physicians who provide interpretation or supervision services only. We recognize that these physicians may affect, among other things, a group practice’s ability to comply with the 75 percent physician-patient encounters test because they generally do not see patients. But to exclude physicians who generally do not see patients would undermine the purpose of the test, which is to ensure that group practices are first, and foremost, joint medical practices for the provision of physician services to patients and not primarily designated health care services enterprises. The Congress addressed the special circumstances of pathologists, diagnostic radiologists, and radiation oncologists in a separate provision. (See discussion of section 1877(h)(5)(C) in section III.B of this preamble).

Comment: A commenter sought clarification that physicians who are employees of their own individual professional corporations instead of the group practice are considered “group members.” The definition of a group

member in § 411.351 already includes physicians whose ownership interest in the group is held through an individual professional corporation. Many physicians wish to not only hold ownership interests in an individual professional corporation, but to be employees of these corporations for pension and tax reasons. To avoid potential abuse, the commenter suggested that we add the following parenthetical to the definition of “member of group” in § 411.351: “(including physicians who are employed by an individual professional corporation, as long as the group has legal authority over the terms of the physician’s employment and is legally responsible for services provided by the physician on the group’s behalf).”

Response: We agree with the commenter that these physicians are “members” of the group. If a physician already qualifies as an “owner” of the group through his or her individual professional corporation, then his or her status as an employee or contractor is irrelevant for purposes of qualifying for group practice status. The amendatory language proposed by the commenter is not necessary, although we are revising the regulations text to clarify that a physician who is employed by an individual professional corporation that has an ownership interest in the group practice is a “member of the group.” Physicians who are employed by their own individual professional corporations and who have no ownership interest in the group (directly or through an individual professional corporation), but provide services to the group, are independent contractors and therefore not members of the group.

Comment: A commenter suggested that a physician who opts out of, and is not receiving any payments from, the Medicare program should not be bound by the limitations in section 1877 of the Act, and, thus, should be able to refer to entities with which he or she has a financial relationship. The commenter also asked that we clarify whether a physician who opts out of the Medicare program pursuant to the private contracting authority in the BBA 1997, but continues to practice with a particular group of physicians, is a group “member” for purposes of the physician self-referral law. The commenter reported that we have elsewhere stated that a group physician’s opting out does not affect the ability of the rest of the group members to provide and bill for services they furnish to Medicare beneficiaries. The commenter stated that physicians who reassign benefits to organizations that participate in Medicare may not opt

out, and that consequently physicians who belong to groups that participate in Medicare and who opt out may not bill and accept payments from Medicare beneficiaries through the group practice unless the entire group practice opts out. Thus, a physician who opts out would have to bill under his or her own name instead of through the group.

The commenter also questioned whether a physician's time spent treating Medicare beneficiaries that is billed through the physician's own name must be counted against the amount of time the physician has spent treating other patients of the group practice. (We assume this means that, for the "substantially all test," the commenter wishes to know whether the physician's private billing constitutes "patient care services" provided outside the group context that would affect whether the physician provides substantially all of his or her services through the group and bills substantially all of his or her services under a billing number assigned to the group.)

The commenter urged that we consider physicians who have opted out as "members" of the group practice only for those services furnished through the group, but not count the physician services in calculating whether the group has met the "substantially all test."

Response: We agree with the commenter that a physician who opts out of the Medicare program and is not receiving any payments from the Medicare program is not bound by the limitations in section 1877 of the Act and, therefore, can refer to entities with which he or she has a financial relationship. Section 1877 prohibits only referrals for services "for which payment otherwise may be made under Medicare," and Medicare would not otherwise pay for services under a private contract. The commenter also is correct in stating that when a group physician has opted out, it does not affect the ability of the rest of the group members to furnish and bill for services they furnish to Medicare beneficiaries.

The commenter is not correct, however, that when a group physician has opted out, the group may not bill in its own name for services provided by the opt-out physician under a private contract. The Medicare statute does not prevent an opt-out physician's group—regardless of whether the group has a participation agreement with Medicare—from billing payers other than Medicare for services furnished under a private contract. Of course, neither the physician nor the group is allowed to bill Medicare for services

furnished under a private contract. Thus, a physician who opts out can remain a group member during the time he or she provides services to group patients, provided the services are billed through the group practice to payers other than Medicare. We believe the requirements in the group practice definition are meant to demonstrate that the physicians involved in the group are actually practicing medicine together. A physician can demonstrate a significant level of participation by treating either program or nonprogram patients, as long as they are group patients.

We also believe that any services the physician bills in his or her own name are not group services and, therefore, should be factored into the "substantially all test" as outside patient care services.

Comment: Several commenters were concerned about the proposed rule's effects on nonprofit medical foundations, particularly in light of our statement that a group practice can consist of only *one* legal entity. One commenter was specifically concerned about medical foundations in California, where such entities are established so that practices can comply with the corporate practice of medicine prohibition. One of the key exceptions to the prohibition allows nonphysician ("lay") participation in arranging for the delivery of physician services if the nonphysician is a qualified medical foundation. (These entities are nonprofit and exempt from Federal income taxation under section 501(c)(3) of the Internal Revenue Code). In California, for example, these foundations provide patient care through a separate, contracted medical group that is comprised of at least 40 physicians who collectively practice in at least 10 specialty areas. A chief concern was that our proposed rules would prevent the nonprofit foundation-model group practice from furnishing DHS under the in-office ancillary services exception because it has no employed physicians or physician owners who can qualify as "members of the group" for purposes of the group practices definitional tests.

The commenter considers the California nonprofit medical foundation to be, in essence, one bifurcated medical services provider that should be treated as a "single legal entity" for purposes of section 1877 of the Act. That is, under California law, the medical foundation is itself a health care provider; yet this can only work if the medical foundation encompasses the physicians who contract to provide the professional services. The IRS currently regards the physician-foundation relationship as comprising an integrated whole and

grants tax-exempt status to those truly integrated foundations as providers of professional medical care. The foundation operates and owns all elements of the practice, but cannot provide the physician services, and the physicians have agreed to furnish all patient care services through the foundation model; it is the foundation, and not the physicians, who own the medical practice.

The commenter stated that entities such as management service organizations do not merit tax-exempt status because they support the provision of services, but do not actually provide services, while the foundations actually provide services. The IRS scrutinizes the entire foundation relationship to assure that its interdependent functions and operations comply with the fundamental requirements for tax exemption.

Response: As an initial matter, that an arrangement is subject to IRS regulation is not determinative under section 1877 of the Act. The IRS's goals in regulating business structures do not necessarily take into account preventing fraud and abuse in the Medicare and Medicaid programs. As to foundation-model practices in corporate practice of medicine States, we recognize that they present special problems under section 1877 of the Act. On the one hand, section 1877(h)(4)(A) clearly authorizes group practices that are "foundations." On the other hand, in the typical foundation-model arrangement, the physicians are not legally organized as a "foundation."

In reviewing the statute and legislative history, we have reached the following conclusions. First, the Congress used the term "foundation" in the group practice definition in a generic sense to cover any situations in which the single legal entity, that is, the group practice, consists of a foundation; the reference was not necessarily intended to encompass bifurcated foundation-model arrangements. Second, the Congress intended for foundation-model arrangements to be excepted under the personal service arrangements exception. The OBRA 1993 Conference Report states that the "conferees intend that this exception [personal service arrangements] would apply to payments made by a nonprofit Medical Foundation under a contract with physicians to provide health care services and which conducts medical research." H. Rep. No. 213, 103d Cong., 1st Sess. 814 (1993).

The personal service arrangements exception should provide foundation-model arrangements with additional

flexibility in structuring their arrangements and that most foundation-model arrangements will be able to fit in the exception, in accordance with the congressional intent. The "volume or value of referrals" and "other business generated" standards will apply uniformly to all exceptions in which they are included. (See the discussion in section V of this preamble and the regulations at § 411.354(d).)

Comment: Several commenters noted that another arrangement commonly used in corporate practice of medicine States is the use of "friendly" or "captive" PCs to create hospital-affiliated group practices in States that prohibit hospitals from employing physicians directly. For example, a commenter explained that in Ohio, a single physician may own stock in a PC, but hold the stock in trust for a hospital or other nonprofit corporation. The PC itself employs physicians who operate as a group practice and would fulfill all of the other group practice requirements. The commenter suggested that this arrangement would satisfy section 1877 of the Act if the rule were changed to permit groups to be owned by a single physician owner.

Response: As noted in section VI.C.2 of this preamble, we have made the change suggested by the commenter. Group practices may be owned by a single physician provided that the group practice employs at least one other physician. Therefore, we believe that "friendly" or "captive" PCs can qualify as group practices if they meet all of the other conditions of the group practice definition.

Comment: Several commenters noted that the sole owner of the "captive" or "friendly" PC may be a hospital-based physician who does not practice medicine as part of the group. These commenters wondered whether a nonparticipating physician owner would be a member of the group for purposes of the group practice definitional tests, particularly the "substantially all test."

Response: We believe that a hospital-based physician, who does not practice medicine as part of the group, is not a member of the group practice for purposes of the definitional tests. However, that means that the physician is not a member for any other purpose either. Thus, for example, a captive or friendly PC owned by such a physician would need to employ at least two physicians to qualify as a group practice. In addition, the sole physician owner described in the comment would not be eligible for sharing in overall profits or productivity bonuses under

section 1877(h)(4)(B)(i) of the Act and § 411.352(i) of the regulations.

Comment: Commenters generally supported our position in the proposed regulations that a physician's financial relationship with an entity under section 1877 of the Act would not be imputed to his or her group practice. Thus, other members of the group practice could continue to make referrals to the entity, provided that the members did not have financial relationships with the entity and the physician with the financial relationship was not in a position to control the referrals of other group members. However, one commenter suggested that we include as members (who could continue to make referrals) physicians who are employed by their own PC (instead of the group) as long as the group has legal authority over the terms of the physician's employment and is legally responsible for services provided by the physician on behalf of the group. This commenter noted that for tax and pension reasons, many physicians prefer to be employed by their PCs rather than the group practice entity.

Response: We are adopting the position we discussed in the proposed regulations, that is, that a physician's financial relationship with an entity under section 1877 of the Act will not be imputed to his or her group practice. Thus, other members of the group practice can continue to make referrals to the entity, provided that the members do not have financial relationships with the entity and the physician with the financial relationship is not in a position to control the referrals of other group members. As we have indicated elsewhere in this preamble, physicians who are employed by their own individual PCs are considered members of the group if the PC has an ownership interest in the group. If not, the physician would be considered an independent contractor who is not a member of the group.

4. The "Full Range of Services Test"

Existing Law: The definition of a group practice in section 1877(h)(4)(A)(i) of the Act provides that, among other requirements, each physician who is a member of the group must provide substantially the full range of services that the physician routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment, and personnel. In the August 1995 final rule covering referrals for clinical lab services, we required physician members to furnish the full range of

"patient care services," defined as services addressing the medical needs of specific patients.

The Proposed Rule: In the January 1998 proposed rule, we proposed expanding "patient care services" to include any physician's tasks that address the medical needs of specific patients or patients in general or that benefit the practice. These activities could include, for example, time spent training group staff members, arranging for equipment, or performing administrative or management tasks, as long as these activities benefit the operation of the group practice. Services wholly outside the group's medical practice, such as teaching, do not count as patient care services. This proposed test was designed to ensure that a physician is actually practicing medicine as he or she ordinarily would as part of the group and has not simply joined the group in name only. It further ensures that physicians are practicing as part of the group and not simply using the group to profit from DHS referrals.

The Final Rule: We are promulgating the test as proposed in the January 1998 proposed rule.

Comment: Commenters generally favored our proposal to revise the definition of "patient care services" to include any physician task that addresses the medical needs of specific patients or patients in general, or that benefits the group practice. However, commenters requested clarification whether activities that are conducted outside the group practice, such as teaching, overseeing residents, or conducting medical research, but that nonetheless benefit patients in general, are covered within the definition. Other similar activities might include administrative positions within hospital systems or independent physicians' associations that involve oversight of patients beyond those of the group practice.

Response: It does not appear to us that the activities listed by the commenter would particularly benefit group practice patients, except possibly in a very attenuated way. (The answer might change if the group itself was contracted to perform these "outside" tasks.) Therefore, we would generally not regard them as patient care services performed for the group. Instead, they might qualify as patient care services provided outside of the group. For example, the physician could be supervising residents in a hospital while the residents treat patients, the volunteer activities might involve treating indigent patients, or the administrative work could involve

overseeing the efficient delivery of care to patients.

If the physician furnishes patient care services exclusively within the group, then whatever services he or she furnishes should constitute the full range of that physician's routine patient care services. If the physician furnishes patient care services both inside and outside of the group, then the services for the group's patients should be comparable in scope to those provided outside of the group setting. Any of a physician's services that do not involve caring for patients should not affect this test. For example, if a physician teaches medicine outside of the practice, but does not oversee patient care, we would not expect that the physician would also be performing teaching services as part of his or her group services.

5. The "Substantially All Test"

The Existing Law: Under the definition of a "group practice" in section 1877(h)(4)(A)(ii) of the Act, substantially all of the services of the physician members must be provided through the group and billed under a billing number assigned to the group, and amounts so received must be treated as receipts of the group. In § 411.351, we interpreted "substantially all" to mean at least 75 percent of the total patient care services of the group practice's members. We promulgated special rules for group practices located solely in HPSAs and for physician members' time spent providing services in HPSAs.

The Proposed Rule: We proposed measuring patient care services (using the same definition of "patient care services" applied in the full range of services test described above) by the "total patient care time" each member spends on these services. We concluded that patient care time was the most straightforward and least burdensome method for measuring a physician's patient care services, but we solicited comments on other viable methodologies. Again, this test ensures that physicians who are members of the group practice are economically bound to the group for other than DHS referrals and are not just members of the group for purposes of profiting from DHS referrals.

The Final Rule: We are promulgating this test as proposed in our January 1998 proposed rule, except as discussed in this preamble. As proposed in our January 1998 proposed rule, the "substantially all test" could be measured based on the member physician's actual time spent performing patient care services, whether performed inside or outside the

group practice. Having reviewed the comments regarding alternative methods for meeting the test, we are amending the "substantially all test" to allow group practices greater flexibility. While "actual time spent" remains the default standard, group practices may adopt alternative measures, provided those measures are reasonable, fixed in advance of the performance of the services being measured (that is, no *ex post facto* methods), uniformly applied over time, verifiable, and documented. Independent contractors and leased employees are not defined under the final rule as members of the group; therefore, their services need not be counted for purposes of complying with the "substantially all test."

Comment: Many commenters appreciated our expansion of the definition of patient care services to include services that benefit group patients in general or the group practice itself, but suggested that group practices be allowed to adopt alternative methods for measuring compliance with the 75 percent "substantially all test," depending on the particular circumstances of the group and the most reasonable manner available for the group. These commenters pointed out that many physicians do not maintain time records and to do so would create an unnecessary administrative burden. Additionally, some commenters believe that it would be difficult or misleading to calculate the exact number of patient care hours as we suggested in the proposed regulations because many full-time physicians tend to work more than 40 hours per week. (Data submitted by a major physician trade association reflected that the "average" physician works 57.9 hours a week, with 53.2 hours spent on patient care activities). For example, one physician in a practice may work a full-time schedule of 40 hours per week for the group and another 60 hours per week; it would be inconsistent to count both as furnishing the same 100 percent of their time to the practice. Alternatively, a physician may work a full 40-hour week at his or her practice and then an additional 20 hours at a hospital or clinic. To count this physician as working only two-thirds time for the group, based on a straight calculation of hours, would be unreasonable. One commenter thought that the regulations should establish a presumption that 40 hours per week of patient care time for physicians equals 100 percent of such time for purposes of calculating the 75 percent "substantially all test"; any hours spent beyond 40 hours on professional patient care time would fall outside of the 75 percent

"substantially all test." Some groups expressed a preference for using relative value units (RVUs) to measure patient care services, while others preferred a revenue based calculation or a test based on patient encounters furnished and billed through the group. One commenter thought that the "patient care time" standard was ambiguous and not objectively verifiable, since physician timekeeping often does not account for time spent on activities not involving direct patient care.

Response: We are persuaded that it would be appropriate to permit group practices additional flexibility in measuring compliance with the "substantially all test" based on their unique circumstances. The "actual time spent" standard described in the preamble of the January 1998 proposed rule remains the default standard. Group practices that employ that standard can be assured that they are appropriately measuring "patient care services." As we noted in the January 1998 proposed rule, we are not requiring that physicians use detailed time sheets or time cards; in most cases, appointment calendars, personal schedules, billing records, or other existing sources will be sufficient to establish the time spent on patient care services. Group practices may adopt alternative means of satisfying the "substantially all test," provided the means used are (1) reasonable, (2) fixed in advance of the performance of the services being measured (that is, no *ex post facto* methods), (3) uniformly applied over time, and (4) verifiable. The data used to calculate compliance with the "substantially all test" and supporting documentation must be made available to the Secretary upon request.

Comment: Several commenters sought clarification whether the 75 percent "substantially all test" for patient care services is measured based on total patient services across all specialties in a group or whether it is measured on a specialty-by-specialty basis.

Response: Section 1877(h)(4)(A)(ii) of the Act provides that a group practice is a legally organized entity "for which substantially all of the services of the physicians who are members * * * are provided through the group * * * ." In § 411.351, we interpreted "substantially all" to mean at least 75 percent of the total patient care services of each of the group practice's members. It is our view that a group practice should aggregate all of the patient care services that each of its members provides, both inside and outside of the practice, including all varieties of patient care services, to determine whether 75 percent of those